HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING JULY 24, 2013 APPLICATION SUMMARY

NAME OF PROJECT:

Wellmont Cardiology Services, Inc.

PROJECT NUMBER:

CN1304-013

ADDRESS:

2050 Meadowview Parkway

Kingsport (Sullivan County), TN 37660

LEGAL OWNER:

Wellmont Health System

c/o Wellmont CVA Heart Institute

2050 Meadowview Parkway

Kingsport (Sullivan County), TN 37660

OPERATING ENTITY:

Not Applicable

CONTACT PERSON:

John Welborn

(615) 665-2022

DATE FILED:

April 15, 2013

PROJECT COST:

\$1,074,000.00

FINANCING:

Cash Reserves

PURPOSE FOR FILING:

Initiation of Positron Emission Tomography (PET)

services and the establishment of an Outpatient

Diagnostic Center (ODC)

DESCRIPTION:

Wellmont Cardiology Services (WCS), Inc. is seeking approval to purchase one (1) of two (2) existing PET scanners owned by LifeScan Tennessee, LLC located at 830 Suncrest Drive, Suite 1, Gray (Washington County), TN and relocating the PET scanner a distance of 10.6 miles to 2050 Meadowview Parkway, Kingsport (Sullivan County), TN. The applicant will also establish an Outpatient Diagnostic Center (ODC) to offer PET services.

SPECIFIC CRITERIA AND STANDARDS REVIEW:

POSITRON EMISSION TOMOGRAPHY SERVICES

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

The applicant projects it will perform 1,500 PET procedures in the first year of operation, 2014. The applicant's PET procedure projections in the second year of operation, 2015, will remain at 1,500.

It appears the applicant will <u>meet</u> the criterion in the first year, but <u>not</u> in the second year.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

The applicant provides a table of the distance and drive time from the proposed PET location (Kingsport, TN) to 9 major cities within the service area. The driving distance ranges from 20.2 miles to Johnson City (Washington County), TN to 38.5 miles to Greeneville (Greene County), TN.

The applicant proposed Virginia service area counties are Wise, Scott, Russell, Lee and Smythe. The provider in the Virginia service area with a PET service is Johnson Memorial Medical Center in Abingdon, VA. The

applicant states it is believed the Johnson Memorial Medical Center does not perform cardiac PET scans. The applicant states this proposed PET project will not adversely impact any Virginia PET because the proposed PET will consist exclusively of its own existing patients.

It appears that this criterion has been met.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

There is no shared service option that is accessible to WCS physicians who must be on-site to supervise PET procedures.

It appears that this criterion has been met.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

The proposed PET is for cardiac PET procedures.

This criterion does not apply.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or, mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

The applicant is not requesting an additional PET unit to the service area.

It appears this criterion does not apply to the proposed project.

- 6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

A FDA approval letter was included in the attachments to the application.

It appears that this criterion has been met.

b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

A letter from an Architectural Firm indicating compliance with current building codes and healthcare guidelines applicable to the project are included in the attachments to the application.

It appears that this criterion has been met.

c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

The applicant provided a copy of the Cardiac PET Clinic Emergency protocols in the supplemental response.

It appears that this criterion has been met.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

Protocols to assure medical appropriateness and medical necessity were included in the attachments to the application.

It appears that this criterion has been met.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by

WELLMONT CARDIOLOGY SERVICES, INC.

CN1304-013 July 24, 2013 PAGE 4 physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

The applicant indicates a Medical Director for the PET service has not yet been identified. A Cardiac PET Medical Director Job Description is provided in the attachments.

It appears that this application intends to meet this criteria.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

The applicant will seek a transfer agreement with Hoston Valley Medical Center if licensed as an ODC. When a Medical Director is hired that person's privileges at Holston Valley Medical Center (HVMC) located in Kingsport, TN will be required by contract.

It appears that this application intends to meet this criteria.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant states it will comply with all requests from the HSDA for timely data.

It appears that the applicant intends to meet this criteria.

- 8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

The applicant provides documentation from the U.S. Health Resources and Services Administration that designates the following medically underserved areas: an MUA designated area of Bethesda Division Service Area within Washington County, TN, an unknown MUA area within Hawkins County, TN, and two MUA areas named Balleytown and Mohawk Division Service area within Greene County, TN.

It appears that this criterion has been met.

b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

The applicant did not request special consideration for this standard.

c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

The applicant is not a hospital. Criterion not applicable.

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant indicates the ODC will participate in all area TennCare MCOs and in Medicare.

It appears that this criterion has been met.

OUTPATIENT DIAGNOSTIC CENTERS

1. The need for outpatient diagnostic services shall be determined on a county by county basis (with data presented for contiguous counties for comparative purposes) and should be projected four years into the future using available population figures.

The applicant indicates there is no publicly available data on either the number, incidence rates of cardiac PET studies within the reported total of PET studies. Thus making it not possible to do an accurate population based population based projection. The applicant did calculate a need of 1,353 Cardiac PET scans in the five county area in 2012. A table by county is provided on page 23 a-r.

There is not sufficient data to determine if this criterion is met.

2. Approval of additional outpatient diagnostic services will be made only when it is demonstrated that existing services in the applicant's geographical service area are not adequate and/or there are special circumstances that require additional services.

The applicant states the current physical PET location in Gray, Tennessee is not an adequate option for WCS cardiologists. The Wellmont Hoston Valley Medical Center mobile PET unit restricts the number of cardiac PET scans that can be scheduled (no more than 300 per year).

It appears that this criterion has been <u>met.</u>

- 3. Any special needs and circumstances:
 - a. The needs of both medical and outpatient diagnostic facilities and services must be analyzed.

The applicant states the only PET in Gray, TN is too far away to allow WCS physicians to routinely go there to medically supervise PET scans. If approved, the companion PET application, Molecular Imaging Alliance will relocate the existing PET to Johnson City (Washington County), TN.

It appears that this criterion has been met.

b. Other special needs and circumstances, which might be pertinent, must be analyzed.

The applicant indicates no special needs and circumstances have been identified other than those listed above in 3a.

- c. The applicant must provide evidence that the proposed diagnostic outpatient services will meet the needs of the potential clientele to be served.
 - 1. The applicant must demonstrate how emergencies within the outpatient diagnostic facility will be managed in conformity with accepted medical practice.

The applicant provided a copy of the Cardiac PET Clinic Emergency protocols in the supplemental response.

It appears that this criterion has been met.

2. The applicant must establish protocols that will assure that all clinical procedures performed are medically necessary and will not unnecessarily duplicate other services.

The applicant provided draft protocols in criterion 6.d of the PET CON review standards and criteria.

It appears that this criterion has been met.

SUMMARY:

The applicant, Wellmont Cardiology Services, Inc. proposes to purchase an existing cardiac PET scanning system now operating at the Molecular Imaging Alliance ODC in Gray (Washington County), TN and relocate the system 10.6 miles into renovated space. The PET system will be positioned in an office building known as "The Heart Center" located at 2050 Meadowview Parkway, Kingsport (Sullivan County), TN. The applicant indicates the project can be open for patient service by January 1, 2014.

Molecular Imaging Alliance (owned by Lifescan, LLC) was originally approved during the April 25, 2007 Agency meeting to establish an ODC and initiate PET services with one PET system. The second PET system was acquired by LifeScan, LLC in April 2008 at a cost of \$150,000. The second PET system acquired by LifeScan did not require CON approval since it was under the \$1,500,000 medical equipment threshold requirement that was in effect during 2008.

Molecular Imaging Alliance, has filed a companion application (CN1304-013) to also be heard at the July 24, 2013 Agency meeting for the relocation of its Outpatient Diagnostic Center (ODC) and one of their own two existing positron emission tomography (PET) scanners from 830 Suncrest Drive, Suite 1, Gray (Washington County), TN to the "701 Building" State of Franklin Road, Suite 1, Johnson City (Washington County), TN, a distance of 10.6 miles. The two related projects will not increase the number of PET/cardiac PET units operating in the proposed service area.

There are key differences in the two applications, Wellmont Cardiology Services, Inc. (CN1304-013) and Molecular Imaging Alliance (CN1304-014): 1) Wellmont Cardiology Services, Inc. (a physician practice) will be addressing the Outpatient Diagnostic Center and PET Criteria and Standards since a change of ownership of the PET scanner will occur resulting in this applicant establishing an ODC and initiating PET services, and 2) Molecular Imaging Alliance will be addressing Construction, Renovation, Expansion, and Replacement of Health Care Institutions criteria since need has already been established and the site is relocating within the same county with no change in ownership.

Note to Agency members: On page 8 of the application, the applicant states the sale of the second cardiac PET system to WCS from LifeScan is conditional on CON approval for both PET systems to be relocated, one to Johnson City, TN (Molecular Imaging Alliance, CN1304-014) and one to Kingsport, TN (Wellmont Cardiology Services, Inc., CN1304-013).

The applicant describes Wellmont Cardiology Services, Inc. as a not-for-profit physician practice owned by Wellmont Health System consisting of forty-seven (47) cardiologists, cardiovascular, vascular, and cardiothoracic surgeons, and twenty-three (23) nurse practitioners and physician assistants that served 45,000

active patients in 2012. The Wellmont Health System is a tertiary health system serving Upper East Tennessee and southwest Virginia residents through a network of providers and facilities in multiple counties.

The hours of operation for the ODC are weekdays 7:00 am to 5:00 pm. The PET scanner being relocated is an eleven year old Siemens 2000 LS-EXCAT system that includes the camera, workstation, software, water chiller unit, lead door and in-lab furniture. The PET scanner is valued at a fair market value of \$350,000.

The applicant indicates the reason for the relocation is to improve the physical accessibility of cardiac PET services for both patients and cardiologists (who must be present during the test). The applicant states cardiologists must be present during SPECT and PET studies because of the risk of patient cardiac arrest during the "stress" part of the test. In the supplemental response the applicant states the region's only PET in Gray is too far away to allow WCS physicians to routinely go there to supervise patient's PET scans. The existing PET scanners are currently located in Gray, TN which the applicant describes as a "small town between Johnson City, TN and Kingsport, TN".

The applicant indicates a mobile PET/CT with cardiac PET capabilities comes several days a week to Holston Valley Medical Center in Kingsport, several miles north of WCS's Heart Center office building. HSDA review of the Holston Medical Center PET utilization for 2012 indicates the scanner operated part-time three days per week providing 1,677 procedures at 175% of the minimum annual treatment utilization as specified by the State Health Plan Standard of 1,600 procedures per full-time unit. In the supplemental response, the applicant states patients cannot gain access to cardiac PET on Holston Valley's PET because that service allows only six cardiac test patients a week (300 patients/year) due to its high utilization and the need to give priority to oncology patients. As of April 26, 2013, the applicant reported WCS patients were backlogged facing a two-month wait for access to the mobile PET. The distance from the proposed project site of WCS on Meadowview Parkway to the Holston Valley Medical center campus is 4.3 miles.

The proposed ODC will contain a cardiac PET camera room with an adjoining control room, a nuclear medicine "hot lab", a dressing room, a patient prep room, a bathroom, a reception and waiting area with administrative/medical records space.

Wellmont Cardiology Services, Inc. will obtain the radiopharmaceutical agents needed for the PET/CT service (N-13 Ammonia for cardiac patients) from Precision Nuclear, LLC which operates a cyclotron on-site in Gray, TN. According to the applicant, Precision Nuclear, LLC is the only cyclotron east of Knoxville, TN. A letter dated April 15, 2013 from Precision Nuclear, LLC states

the applicant will continue to be supplied with N-13 Ammonia for cardiac PET perfusion at the proposed Kingsport location. In the supplemental response, the applicant projects the cost of the pharmaceutical agent N-13 will total \$480,000 or \$320.00 per patient. The stress agent Lexiscan is projected to cost \$90,000 or \$60.00 per patient. The applicant states Wellmont Cardiology Services, Inc. has no long-term plans to include a cyclotron on-site at the proposed location.

The applicant states that the primary service area (PSA) includes four (4) Tennessee Counties, including Greene, Hawkins, Sullivan and Washington Counties. The applicant has also included Washington, Wise, Scott, Russell, Lee and Smyth Counties in Southwest Virginia in the proposed service area. Patients residing in Washington County (Tennessee) are expected to account for the majority of the Tennessee projected utilization in Year One and Year Two of operations (approximately 26.8% of total PET procedures). According to projections based upon the U.S. census 2010 data, the four county service area population is estimated to be 414,149 in 2013 and projected to grow to 426,365 in 2017, a 2.9% increase. The total population in Tennessee overall is also expected to grow 3.7% during this time frame. HSDA identifies 71,007 TennCare enrollees in the service area which is equivalent to 17.1% of the population. The range of TennCare enrollees as a % of total population by county is 14.8% in Washington County and 20.7% in Hawkins County. The TennCare enrollees as % of total population for Tennessee overall in June 2012 was 18.6%.

If both of the companion applications are approved, Wellmont Cardiology Services, Inc. and Molecular Imaging Alliance will share Greene, Sullivan and Washington counties in their primary service area. In the supplemental response, the applicant states the proposed Molecular Imaging Alliance PET relocation to Johnson City (Washington County) will not reduce the PET utilization projections of Wellmont Cardiology Services, Inc. The chart below reflects the primary service area and the 2012 existing practice patient origin of both providers.

Primary Service Area and Patient Origin for Proposed Projects Molecular Imaging Alliance and Wellmont Cardiology Services, Inc.

				17	Carul	l services, i	itt.	1
	Carter	Greene	Hawkins	Sullivan	Unicoi	Washington	Other TN Counties/ States	Virginia
Molecular Imaging Alliance (CN1304- 014)	X	X		X	x	X		
Patient Origin	17.8%	7.8%		6.0%	8.1%	49.4%	10.9%	0%
Wellmont								
Cardiology Services, Inc. (CN1304- 013)		X	X	x		x	*	
Patient Origin		7.3%	8.0%	26.8%		8.4%	15.8%	33.7%

Source: CN1304-013 and CN1304-014

As reflected in the table above, the applicant expects the majority of its PET utilization (33.7%) will come from residents crossing the Tennessee state line from the State of Virginia.

PET equipment utilization recently reported by the HSDA for PET units in the primary service area is shown below:

13

PET Utilization in the 4-County Tennessee PSA

				2010	2011	2012	'10-'12	2012
County	Provider	Fixed Units	Mobile units (days/wk)	Procs.	Procs.	Procs.	% change	% of Standard
Greene	Laughlin Memorial	None	1 (2 days/wk)	456	430	351	-23%	54.8%
Sullivan	Bristol Reg.Med. Ctr.	None	1 (2 days/wk)	435	466	460	+5.7%	71.9%
Sullivan	Holston Valley Medical Ctr.	None	1 (3 days/wk)	1,381	1,501	1,677	+21.4%	175%
Sullivan	Indian Path Medical Ctr.	None	1 (1 day/wk)	154	133	143	-6.5%	44.7%
Washington	JCMC	1	None	1,769	1,542	1,234	-30.2%	77%
Washington	LifeScan Tennessee, LLC	2	None	342	514	623	+82%	19.4%
Totals		3 fixed	4 mobile	4,537	4,586	4,488	-1.1%	61%

The State Health Plan Certificate of Need PET Standards and Criteria indicate "applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to 1,600 procedures per year by the second year of service and every year thereafter."

Of the six PET providers, only one reported the minimum annual treatment utilization as specified by the *State Health Plan* Standard of 1,600 procedures per full-time unit annually after two years of being in service. Utilization of PET services appears to be trending slightly downward for the service area from 4,537 procedures in 2010 to 4,488 procedures in 2012, or -1.1%.

The Projected Data Chart provided in the application for Wellmont Cardiology Services, Inc. projects net operating gains after capital expenditures of \$242,593 during the first year of operation and \$220,693 during the second year of operation. The applicant expects to realize \$5,517,435.00 in total gross revenue on 1,500 PET procedures in Year One and the identical amount of total gross

WELLMONT CARDIOLOGY SERVICES, INC.

CN1304-013 July 24, 2013 PAGE 13 revenue and procedures Year Two of the project. After contractual adjustments, charity and bad debt (total average annual deduction of approximately \$2,538 per procedure), annual net operating revenue averages approximately \$1,710,405.00 per year or \$1,140.00 per PET procedure for Year One and Year Two. Management Fees total \$131,312 in Year One and Year Two, respectively. Staffing for the PET/CT in Year Two will consist of 1.0 full-time RN and a 1.0 full-time Nuclear Med Technologist.

The proposed gross charge per procedure in Year One and Year Two is \$3,678.00. According to the 2012 HSDA Medical Equipment Registry, the gross charge is slightly above the 1st quartile gross charge per procedure of \$3,667.96. The chart below reflects the 2012 1st quartile, median and 3rd quartile gross charge per procedure for all statewide PET providers.

Gross Charges per Procedure/Treatment By Quartiles 2012

Equipment Type	1st Quartile	Median	3rd Quartile
PET Scanner	\$3,667.96	\$4,497.71	\$6,304.71

Source: Medical Equipment Registry - 6/28/2013

Wellmont Cardiology Services, Inc. is contracted with BlueCare, United Community Healthcare Plan, TennCare Select and Medicare. In addition, the applicant is contracted with the Virginia Medicaid Plan. It is anticipated that during the first operational year following the project's completion, projected Medicare revenues are anticipated to be \$3,795,995 (68.8% of total gross revenues), while TennCare/Medicaid revenues are anticipated to be \$187,593 (3.4% of the project's gross revenues). In addition, Wellmont Cardiology Services, Inc. has budgeted \$193,110 (3.5% of the project's gross revenues) for charity care within the first year of the project which is equivalent to fifty-two (52) PET procedures.

Approximately 847 square feet of the ODC's 4,214 SF of space will be renovated. Renovation will include radiation shielding installation in the walls of the PET camera room, nuclear medicine hot lab, patient prep room and uptake waiting rooms. The facility renovation cost is estimated at \$520,000 or approximately \$250 per square foot. In a letter dated April 12, 2013, the Architectural Firm Cain Rash West states the proposed facility will meet current applicable building codes as well as guidelines for Design and Construction of Health Care Facilities. The total estimated project cost is \$1,074,000.00 which includes \$546,000 for construction and contingency costs; \$30,000 for architectural and engineering

WELLMONT CARDIOLOGY SERVICES, INC.

CN1304-013 July 24, 2013 PAGE 14 fees, \$30,000 for Legal, Administrative and Consultant Fees, \$325,000 for fixed equipment, \$60,000 for moveable equipment, \$80,000 for moving and miscellaneous expenses and \$3,000 for CON filing fees.

The proposed project will be funded through the cash reserves of Wellmont Health System. A letter dated April 15, 2013 from Wellmont Health System's Senior Vice President of Finance noted the availability of \$1,074,000 in cash to cover the capital cost required to implement this proposed project. The applicant provided the Wellmont Health System and Affiliates audited financial statements for the period ending June 30, 2012 which indicates a balance of Cash and Cash Equivalents of \$44,930,000 and a current ratio of 1.81:1. Current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

The applicant has submitted the required information on corporate documentation, lease, and manufacturer's quote including maintenance contract, and FDA approval. Staff will have a copy of these documents available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency's office.

Should the Agency vote to approve this project, the CON would expire in two years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent, pending or denied applications, or outstanding Certificates of Need for this applicant.

<u>CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA</u> FACILITIES:

There are no other Letters of Intent, denied applications, or outstanding Certificates of Need for other health care organizations proposing this type of service.

Pending Applications

Molecular Imaging Alliance, CN1304-014, has a pending application that will be heard at the July 24, 2013 Agency meeting for relocation of an Outpatient Diagnostic Center (ODC) with cardiac PET scanning from 830 Suncrest Drive, Suite 1, Gray (Washington County), TN to 701 N. State of Franklin Road, Suite 1, Johnson City (Washington County), TN. The estimated project cost is \$495,339.00.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PME (07/14/13)

LETTER OF INTENT

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Times News, which is a newspaper of general circulation in Sullivan County, Tennessee, on or before April 10, 2013, for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Wellmont Cardiology Services, Inc. (a not-for-profit corporation and physician group practice), wholly owned and operated by Wellmont Health Systems dba Wellmont CVA Heart Institute (a not-for-profit corporation), intends to file an application for a Certificate of Need to (a) acquire an existing cardiac PET system now serving patients in Gray, Tennessee, and to (b) relocate that PET system to, and initiate cardiac PET services at, the Wellmont CVA Heart Institute building at 2050 Meadowview Parkway, Kingsport, TN 37660, and to (c) establish an Outpatient Diagnostic Center ("ODC") to offer that PET service at that site, if required by the Tennessee Department of Health. The project's capital cost is estimated at \$1,100,000.

If required, the applicant will seek licensure of this cardiac PET facility as an Outpatient Diagnostic Center, from the Board for Licensing Health Care Facilities, Tennessee Department of Health. The project does not contain any other type of major medical equipment, or initiate or discontinue any other significant health service. It will not affect any licensed bed complements.

The anticipated date of filing the application is on or before April 15, 2013. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 203, Nashville, TN 37215; (615) 665-2022.

(Signature) (Date) jwds (E-mail A

jwdsg@comcast.net (E-mail Address) COPYApplication
Wellmont
Cardiology
Services

CN1304-013

WELLMONT CARDIOLOGY SERVICES

CERTIFICATE OF NEED APPLICATION
TO ACQUIRE AN EXISTING
CARDIAC PET SCANNING SYSTEM IN
WASHINGTON COUNTY
AND
TO RELOCATE IT TO SULLIVAN
COUNTY (AS AN ODC IF REQUIRED)

Filed April 2013

PART A

1. Name of Facility, Agency, or Institution

Wellmont Cardiology Services, Inc.		
Name		
2050 Meadowview Parkway		Sullivan
Street or Route		County
Kingsport	TN	37660
City	State	Zip Code

2. Contact Person Available for Responses to Questions

John Wellborn		Co	onsultant
Name			Title
Development Support Group	jwdsg@comcast.net		
Company Name		E-N	1ail Address
4219 Hillsboro Road, Suite 203	Nashville	TN	37215
Street or Route	City	State	Zip Code
CON Consultant	615-665-20)22	615-665-2042
Association With Owner	Phone Nun	nber	Fax Number

3. Owner of the Facility, Agency, or Institution

Wellmont Health System		
Name		
c/o Wellmont CVA Heart Insti	tute at same address as in #1 above	
Street or Route		County
Kingsport	TN	37660
City	State	Zip Code

4. Type of Ownership or Control (Check One)

		F. Government (State of TN or	
A. Sole Proprietorship		Political Subdivision)	
B. Partnership G. Joint Venture			
C. Limited Partnership		H. Limited Liability Company	
D. Corporation (For-Profit)		I. Other (Specify):	
E. Corporation (Not-for-Profit)	X		

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS

April 26, 2013 1:15 pm

5. Name of Management/Operating Entity (If Applicable) NA

Name		
Street or Route		County
City	State	Zip Code

6. Legal Interest in the Site of the Institution (Check One)

A. Ownership		D. Option to Lease	
B. Option to Purchase		E. Other (Specify):	
C. Lease of 10 Years	X		

7. Type of Institution (Check as appropriate—more than one may apply)

A. Hospital (Specify): General	I. Nursing Home	
B. Ambulatory Surgical Treatment	(if required)	
Center (ASTC) Multi-Specialty	J. Outpatient Diagnostic Center	x
C. ASTC, Single Specialty	K. Recuperation Center	
D. Home Health Agency	L. Rehabilitation Center	
E. Hospice	M. Residential Hospice	
F. Mental Health Hospital	N. Non-Residential Methadone	
G. Mental Health Residential Facility	O. Birthing Center	U
H. Mental Retardation Institutional	P. Other Outpatient Facility	
Habilitation Facility (ICF/MR)	(Specify):	
	Q. Other (Specify): MD Practice	X

8. Purpose of Review (Check as appropriate—more than one may apply

		G. Change in Bed Complement	
A. New Institution (ODC for Cardiac	х	Please underline the type of Change: Increase, Decrease, Designation,	
PET, if State law requires it)		Distribution, Conversion, Relocation	
B. Replacement/Existing Facility		H. Change of Location	
C. Modification/Existing Facility	X	I. Other (Specify):	
D. Initiation of Health Care Service			
as defined in TCA Sec 68-11-1607(4)			
(Specify) Fixed Cardiac PET	x		
E. Discontinuance of OB Service			
F. Acquisition of Equipment			

9. Bed Complement Data

NA

(Please indicate current and proposed distribution and certification of facility beds.) CON approved **TOTAL Beds** beds Current Beds at Proposed (not in Staffed Licensed Completion (Change) service) **Beds Beds** A. Medical B. Surgical C. Long Term Care Hosp. D. Obsetrical E. ICU/CCU F. Neonatal G. Pediatric H. Adult Psychiatric I. Geriatric Psychiatric J. Child/Adolesc. Psych. K. Rehabilitation L. Nursing Facility (non-Medicaid certified) M. Nursing Facility Lev. 1 (Medicaid only) N. Nursing Facility Lev. 2 (Medicare only) O Nursing Facility Lev. 2 (dually certified for Medicare & Medicaid) P. ICF/MR Q. Adult Chemical Dependency R. Child/Adolescent Chemical Dependency S. Swing Beds T. Mental Health Residential Treatment U. Residential Hospice **TOTAL**

10. Medicare Provider Number:	to be applied for if required
Certification Type:	Outpatient Diagnostic Center
11. Medicaid Provider Number:	to be applied for if required
Certification Type:	Outpatient Diagnostic Center

12. & 13. See page 4

A.12. IF THIS IS A NEW FACILITY, WILL CERTIFICATION BE SOUGHT FOR MEDICARE AND/OR MEDICAID?

The applicant is an existing physician practice entity that already is certified for participation in both Medicare and TennCare/Medicaid.

This applicant does not intend to create a new licensed facility, but rather to move an existing cardiac PET unit, now at a remote location, into the main office of the practice in Kingsport, where it can be utilized more frequently. However, if State law requires licensure of this service as an Outpatient Diagnostic Center, the applicant's ODC will seek the same Medicare and TennCare/Medicaid contract status as the group practice.

A.13. IDENTIFY ALL TENNCARE MANAGED CARE ORGANIZATIONS / BEHAVIORAL HEALTH ORGANIZATIONS (MCO'S/BHO'S) OPERATING IN THE PROPOSED SERVICE AREA. WILL THIS PROJECT INVOLVE THE TREATMENT OF TENNCARE PARTICIPANTS? Yes IF THE RESPONSE TO THIS ITEM IS YES, PLEASE IDENTIFY ALL MCO'S WITH WHICH THE APPLICANT HAS CONTRACTED OR PLANS TO CONTRACT.

DISCUSS ANY OUT-OF-NETWORK RELATIONSHIPS IN PLACE WITH MCO'S/BHO'S IN THE AREA.

Table One: Contractual Relationships with Service Area MCO's		
Available TennCare MCO's / Medicaid	Applicant's Relationship	
BlueCare	contracted	
United Community Healthcare Plan (formerly AmeriChoice)	contracted	
TennCare Select	contracted	
Virginia Medicaid	contracted	

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment

- A cardiology group practice in Kingsport, Wellmont Cardiology Services ("WCS"), proposes to acquire an existing <u>cardiac PET</u> system (not traditional PET/CT) that is currently serving the region's patients at an Outpatient Diagnostic Center (ODC) in Gray, Tennessee in northwest Washington County.
- The system would then be relocated 10.6 miles west, into the Wellmont Cardiology Services ("WCS") practice offices in "The Heart Center" building in Kingsport (south Sullivan County), a distance of 10.6 miles, to provide that diagnostic service to many more WCS patients than can utilize it at its current location in Gray.
- If required by State law, WCS will establish a Licensed Outpatient Diagnostic Center (ODC) in its building to provide cardiac PET scanning.
- The project does not add a PET unit to the area, or a new service to the area or to Sullivan County. It does add fixed cardiac PET and cardiac PET service at a new location within the county and the current service area.

Ownership Structure

• The applicant, Wellmont Cardiology Services, Inc. is a not-for-profit physician practice corporation whose sole member/owner is Wellmont Health System, a not-for-profit healthcare system based in the Tri-Cities area of Upper East Tennessee and Southwest Virginia. The system operates several hospitals in the region, including Holston Valley Medical Center in Kingsport. It is one of the State's largest tertiary healthcare networks. Attachment A.4 contains more details, and information on the Tennessee facilities owned by this facility's parent organization.

Service Area

• The project will not serve any Tennessee counties not already being served by the cardiac PET ODC in Gray. The service's primary service area, when moved to Kingsport, will continue to include Sullivan, Washington, Hawkins, and Greene Counties in Tennessee, and Washington, Wise, Scott, Russell, Lee, and Smyth Counties in southwest Virginia.

Need

• WCS sees an estimated 1,500 patients per year who would benefit from having diagnostic tests on this cardiac PET system. Its current location 10.6 miles east of the WCS offices, in a small town in the adjoining county, discourages its use by WCS

patients and by the WCS cardiologists who must travel with them to supervise the test. Bringing it in-house at WCS's Kingsport office will greatly expand the cardiac PET system's utilization, which currently is far below its optimal capacity. Cardiac PET improves diagnosis, eliminates many interventional procedures, and takes hours less time than the test (SPECT) it is replacing.

- The ODC provider that uses this and a second system at Gray is planning to move farther east into Johnson City, retaining only one system. The second will be sold by the equipment vendor that now leases both systems to the ODC. This is an opportunity for WCS to acquire economically priced and dependable Siemens cardiac PET technology to improve its diagnostic information for all patients who would benefit from it. For some patients, that will prevent unnecessary, risky, and expensive subsequent interventional procedures such as cardiac catheterizations and coronary artery bypass grafts.
- This project will not reduce utilization of the only provider of dedicated cardiac PET services in the region, which is the ODC in Gray. This project has been planned in cooperation with that provider. The ODC and WCS are simultaneously filing CON applications to relocate one cardiac PET system each, to Johnson City and to Kingsport, respectively—to make them more accessible to the majority of patients and referring physicians. There, both systems will be used at much higher capacity.
- The project does not duplicate existing technology or services; it does not serve counties not already being served by this technology. The availability of the service for this region has received CON approval already; the project improves patient accessibility and physician productivity; the project improves the quality of care and provides cost savings in "downstream" interventions; and the project has no adverse impact on other providers. Depending on State law, the project may have to be licensed as an additional ODC--but if so, "splitting" one existing ODC into two will not increase area diagnostic capacity because it will not create additional equipment or services in the area.

Existing Resources

• The only source of this service in all of Upper East Tennessee (The "Tri-Cities" area) is the ODC in Gray. It serves patients from throughout the region, including large numbers of residents of southwest Virginia.

Project Cost, Funding, Financial Feasibility, Staffing

- The project cost for CON purposes is estimated to be \$1,073,410. All this will be provided in cash by the applicant's parent system, Wellmont Health System.
- The financial feasibility of the project is clearly indicated by a strong positive operating margin each of its first two years. This projection relies only on the number of potential patients already being seen at WCS offices, so it is not speculative.
- The project will serve TennCare and indigent patients as well as those with adequate insurance, so financial accessibility is assured.
- The proposed service or ODC will require only three new FTE's--one RN, one nuclear medicine technologist, and a clerical employee.

B.II. PROVIDE A DETAILED NARRATIVE OF THE PROJECT BY ADDRESSING THE FOLLOWING ITEMS AS THEY RELATE TO THE PROPOSAL.

B.II.A. DESCRIBE THE CONSTRUCTION, MODIFICATION AND/OR RENOVATION OF THE FACILITY (EXCLUSIVE OF MAJOR MEDICAL EQUIPMENT COVERED BY T.C.A. 68-11-1601 et seq.) INCLUDING SQUARE FOOTAGE, MAJOR OPERATIONAL AREAS, ROOM CONFIGURATION, ETC.

The Applicant

The CON applicant for this project is Wellmont Cardiology Services, Inc. ("WCS"). WCS is a not-for-profit physician practice corporation whose sole member/owner is Wellmont Health System, a not-for-profit hospital system based in Upper East Tennessee. The Wellmont system is a tertiary health system serving Upper East Tennessee and southwest Virginia residents, through a large network of providers and facilities in multiple counties. Holston Valley Medical Center in Kingsport (Sullivan County) is Wellmont's largest facility. It has been ranked in the top 100 hospitals nationally for cardiac care, major cardiac surgery, heart attack treatment, and coronary bypass surgery. WCS currently provides specialty care to more than 45,000 active patients in the region.

As a physician group practice, WCS has a group provider number, and its own tax ID number. The group's licensed practitioners include 47 cardiologists, cardiovascular, vascular, and cardiothoracic surgeons, and 23 nurse practitioners and physician assistants. Last year WCS had 45,000 active patients. Its main Tennessee office is located in the Wellmont building known as "The Heart Center" at 2050 Meadowview Parkway, Kingsport. It shares space in that building with Holston Valley Medical Center, which operates several diagnostic services there.

Scope of the Service

Cardiac PET has been shown by multiple studies to be the most informative test available for cardiologists who are evaluating certain patients' arterial blockages (perfusion studies), or those patients' ability to successfully accept a coronary artery bypass graft (viability study). Such improved information has been shown to reduce subsequent cardiac catheterization procedures and coronary bypass surgeries.

This project is a change in ownership and location for an existing cardiac PET unit, serving the same service area as before. It is unclear to HSDA and State Licensure staff at this time if that will require the group practice to license the service as an Outpatient Diagnostic Center ("ODC"). To provide for that possibility, this application also requests approval for licensure as an ODC with cardiac PET scanning, if required.

Specifically, WCS proposes (a) to purchase an existing cardiac PET scanning system now operating at the Molecular Imaging Alliance ODC in nearby Gray, Tennessee (northwest Washington County); and (b) to relocate that system into renovated space at the WCS office building known as "The Heart Center" on Meadowview Parkway in Kingsport (Sullivan County). This is a relocation of less than 11 miles across the Sullivan/Washington County line.

The equipment to be purchased is a Siemens 2000 LS-EXCAT PET system. It includes the camera, workstation, software, water chiller, lead door, and in-lab furniture required to perform this type of nuclear medicine evaluation. The equipment is currently owned by LlifeScan Leasing of Tennessee, LLC, which leases two cardiac PET systems to LlifeScan Tennessee LLC's Molecular Imaging Alliance ODC in Gray (northwest Sullivan County). That ODC is located at 830 Suncrest Drive, Johnson City. It offers Upper East Tennessee's only cardiac PET service.

This is not replacement equipment. Molecular Imaging has filed a CON application to relocate to Johnson City, where it will need only one PET system. It has sold its second cardiac PET system to WCS, conditional on CON approval for both PET systems to be relocated--one to Johnson City and one to Kingsport. These two CON applications for service relocations have been filed as companion applications. The two related projects will not increase the number of PET/cardiac PET units operating in the service area. Their combined service areas in the future will be the same as today--the counties of upper East Tennessee plus nearby counties in Southwest Virginia.

The reason for both relocations is to improve the physical accessibility of cardiac PET services for both patients and cardiologists (who must be present during the test). The units are being relocated into the largest cities of Upper East Tennessee, from a small town location midway between those two cities. Improved accessibility is efficient for

both the patient and the patient's cardiologist. It will make it possible to increase substitution of cardiac PET studies for SPECT nuclear medicine studies, for patients who would benefit from the substitution. Use of both cardiac PET units is projected to increase greatly once they are in the two centers of medical care in this region.

It should be added that this is not actually a new type of service for Wellmont patients in Kingsport. A mobile PET/CT service with cardiac PET capabilities comes several days a week to Holston Valley Medical Center in Kingsport, several miles north of WCS's Heart Center office building. Wellmont Health System owns both the hospital and WCS. So as a practical matter, cardiac PET studies are already available to Wellmont patients in Kingsport, though not at the proposed address, or from a fixed PET.

The service will be the first fixed cardiac PET service in Kingsport; and it will be imbedded in the Heart Center with the other diagnostic testing modalities used by WCS cardiologists, where it can operate most efficiently and can reach its maximum utilization potential, enhancing quality of care.

Location and Design of the Project

The cardiac PET system will be installed in existing ground-floor space in the WCS office building (The Heart Center) on Meadowview Parkway. It will occupy 2,080 square feet of space in a corner of the building. It will contain a cardiac PET camera room with an adjoining control room, a nuclear medicine "hot lab", a dressing room, a patient prep room, a bathroom, and a reception and waiting area with administrative/medical records space. The cardiac PET camera room, nuclear medicine hot lab, patient prep room, and uptake waiting rooms will have radiation shielding.

The service will meet all applicable standards in its construction and operation, and will comply with requirements of the Division of Radiological Health (Tennessee Department of Health and Environment). It will seek accreditation for Positive Emission Tomography (PET) services, by the Intersocietal Accreditation Commission (which currently accredits the Molecular Imaging ODC in Gray). A floor plan is provided in Attachment B.IV. at the back of this application.

Table Two-A: Summary of Constru	
	Total Square Feet
Facility Before Project	na
Facility After Project	2,080 SF
Net Increase in Size (%)	na
Area of New Construction	0
Area of Buildout or Renovation	2,080 SF
Total New & Renovated Construction	2,080 SF

Tal	ole Two-B: Constru	ction Costs of This Proje	ect
	Renovation Construction	New Construction	Total Project
Square Feet	2,080 SF	0	2,080 SF
Construction Cost	\$520,000	0	\$520,000
Constr. Cost PSF	\$250	0	\$250

Implementation Schedule and Hours of Operation

The project can be open for patient service by January 1, 2014. The proposed hours of operation (scheduled service) are from 7 AM to 5 PM, on weekdays.

Project Cost and Financing

The cost for CON purposes is estimated at \$1,073,410. Wellmont Health System will provide this in cash.

APPLICANTS WITH HOSPITAL PROJECTS (CONSTRUCTION COST IN EXCESS OF \$5 MILLION) AND OTHER FACILITY PROJECTS (CONSTRUCTION COST IN EXCESS OF \$2 MILLION) SHOULD COMPLETE THE SQUARE FOOTAGE AND COSTS PER SQUARE FOOTAGE CHART....

, Not applicable.

PLEASE ALSO DISCUSS AND JUSTIFY THE COST PER SQUARE FOOT FOR THIS PROJECT.

ODC renovation projects completed in 2008-2012 ranged from \$52-\$196 PSF construction cost, according to data from the HSDA Registry. See Table Three-A below. Although the HSDA Registry did not compile a similar table for 2008-2012 due to the small number of ODC projects (5) completed in 2012, the Registry has supplied construction cost data for those five projects; see Table Three-B below.

Wellmont Cardiology Services' projected renovation cost of \$250 PSF for this very small space is moderately higher than the third quartile range of costs shown in Table Three-A, but is within the range of costs in Table Three-B. It must be recognized that a very small project like this, with large amounts of costly shielding, can be expected to show a relatively high cost per SF compared to larger projects, because larger projects can spread the site mobilization and related fixed costs over a larger square footage.

Table Three	-A: Outpatient Diagno Years: 20	stic Center Constru 008-2010	
	Renovated Construction	New Construction	Total Construction
1 st Quartile	\$51.55/sq ft	none	\$51.55/sq ft
Median	\$122.15/sq ft	none	\$122.15/sq ft
3 rd Quartile	\$196.46/sq ft	none	\$196.46/sq ft

Source: HSDA Registry. CON approved applications for years 2008 through 2010

	hree-B: Outpatient Diagnos Years:	2012	
CON	ODC / Provider	Renovation Area	Construction Cost / sq ft
CN0908-044	ImagDent of Memphis	1,746 SF	\$51.55/sq ft
CN1010-046	Murfreesboro Diagnostic Imaging	9,587 SF	\$122.15/sq ft
CN1010-047	Cleveland Imaging	911 SF	\$269.91/sq ft
CN1103-008	E. TN Community Open MRI	795 SF	\$160.38/sq ft
CN1110-039	St. Thomas OP Imaging	7,737 SF	\$159.69/ sq ft

Source: HSDA Registry. CON approved ODC projects completed in 2012 (all renovation).

IF THE PROJECT INVOLVES NONE OF THE ABOVE, DESCRIBE THE DEVELOPMENT OF THE PROPOSAL.

Not applicable.

B.II.B. IDENTIFY THE NUMBER AND TYPE OF BEDS INCREASED, DECREASED, CONVERTED, RELOCATED, DESIGNATED, AND/OR REDISTRIBUTED BY THIS APPLICATION. DESCRIBE THE REASONS FOR CHANGE IN BED ALLOCATIONS AND DESCRIBE THE IMPACT THE BED CHANGE WILL HAVE ON EXISTING SERVICES.

Not applicable; no inpatient beds are affected by the project.

B.II.C. AS THE APPLICANT, DESCRIBE YOUR NEED TO PROVIDE THE FOLLOWING HEALTH CARE SERVICES (IF APPLICABLE TO THIS APPLICATION):

- 1. ADULT PSYCHIATRIC SERVICES
- 2. ALCOHOL AND DRUG TREATMENT ADOLESCENTS >28 DAYS
- 3. BIRTHING CENTER
- 4. BURN UNITS
- 5. CARDIAC CATHETERIZATION SERVICES
- 6. CHILD AND ADOLESCENT PSYCHIATRIC SERVICES
- 7. EXTRACORPOREAL LITHOTRIPSY
- 8. HOME HEALTH SERVICES
- 9. HOSPICE SERVICES
- 10. RESIDENTIAL HOSPICE
- 11. ICF/MR SERVICES
- 12. LONG TERM CARE SERVICES
- 13. MAGNETIC RESONANCE IMAGING (MRI)
- 14. MENTAL HEALTH RESIDENTIAL TREATMENT
- 15. NEONATAL INTENSIVE CARE UNIT
- 16. NON-RESIDENTIAL METHADONE TREATMENT CENTERS
- 17. OPEN HEART SURGERY
- 18. POSITIVE EMISSION TOMOGRAPHY
- 19. RADIATION THERAPY/LINEAR ACCELERATOR
- 20. REHABILITATION SERVICES
- 21. SWING BEDS

Molecular Imaging Alliance has decided to downsize its cardiac PET capacity to one system, and to relocate its ODC to Johnson City. Molecular's equipment vendor, LlifeScan Leasing, has offered the second system to WCS, which has long wanted such a unit at an affordable price within their Heart Center offices in Kingsport.

Such a unit is appropriate at the Heart Center, because for a large number of patients being diagnosed at the office, substitution of cardiac PET for the more prevalent SPECT test (another nuclear medicine study) yields superior diagnostic information. With improved information, care can be improved and costs can be saved. While WCS has identified approximately 1500 WCS patients a year that would likely benefit from cardiac PET in lieu of SPECT and other studies, it has not been feasible to refer so many to Gray, in the adjoining county, for two reasons. First, not all patients want to make the trip to Gray. Many prefer having all their testing needs met in one continuum of care at the Heart Center. Second, a cardiac PET study requires the presence onsite of the cardiologist; and stationing busy cardiologists out at Gray for hours per day, where they

cannot see other patients to perform other types of patient care, is an inefficiency that is unfeasible for a very large cardiology group practice like WCS. For those reasons, WCS use of the cardiac PET ODC at Gray has been lower than if it were within the Heart Center in Kingsport, under the efficient on-site supervision of its cardiologists.

The value of cardiac PET as a superior option to nuclear medicine SPECT studies (especially for patients of large body mass) has been consistently demonstrated by an array of clinical studies. Excerpts from several professional articles about its efficacy and cost savings are provided in the Attachments to this application--from the Journal of Nuclear Medicine, the Journal of American Cardiology, the Journal of Nuclear Cardiology, and Image (a professional magazine). As the case has built for this modality, more cardiology practices have begun to utilize it. The studies show that for patients considered likely to have coronary artery disease, myocardial perfusion PET is superior to SPECT in terms of image quality, interpretive certainty, and diagnostic accuracy. This is because cardiac PET has higher photon counts, improved spatial resolution, and attenuation correction in its images. With such improved information, the cardiologist can better evaluate the need (and probable efficacy) of additional "downstream" tests and interventions such as cardiac catheterizations and coronary artery bypass surgery.

This equipment acquisition and change of location does not appear to raise any adverse health planning issues; and it furthers several goals of the CON process. Examples include the following.

- 1. Non-proliferation of services: Wellmont Health System already performs PET/CT studies at Holston Valley Medical Center (Wellmont's Kingsport hospital), primarily for oncology purposes. So, although this would be a fixed cardiac PET unit (PET only not PET/CT) at a new Wellmont site, and subject to CON review, it is not technically a new service for the system's patients in Sullivan County.
- 2. <u>Non-duplication of major medical equipment</u>: this cardiac PET system is not a new PET system for the service area; it is already serving patients 11 miles away.

- 3. <u>No new service area</u>: the equipment's relocation to the WCS campus in Kingsport will not cause it to serve any counties that are not already being served from Gray.
- 4. <u>Consistent with prior CON approvals</u>: the cardiac PET units at Gray have already received favorable CON review once already.
- 5. <u>Improves accessibility</u>: the relocation will be more convenient for more patients and for more of the physicians supervising the scans.
- 6. <u>Improves efficiency</u>: a cardiac PET test visit takes about an hour and 15 minutes, compared to three to six hours for a SPECT test visit. Switching to cardiac PET saves patients and their supervising physicians substantial time.
- 7. <u>Improves utilization of major medical equipment</u>: by encouraging more conversion of SPECT studies to cardiac PET studies, the project will increase utilization of the cardiac PET system several-fold. This will be a more efficient use of prior major medical equipment investment.
- 8. <u>Cost savings</u>: studies are showing that cardiac PET rules out coronary artery bypass surgeries and cardiac catheterizations for many patients, and reduce the costs of care in such cases by as much as 30%. (See articles in the Attachments).
- 9. <u>No adverse impact on other providers</u>: because the increased utilization will come from conversion and follow-ups of this practice's own internal SPECT procedures, it will not reduce utilization at any other provider's PET or cardiac PET unit.

Need for an Outpatient Diagnostic Center for Cardiac PET Scanning

According to HSDA staff and Licensure staff, the proposed acquisition and use of this service by a group practice wholly owned by a health system may or may not require that it be certified as an Outpatient Diagnostic Center. The question needs further study. To avoid missing the opportunity to acquire this equipment, the applicant is proceeding with this application, and is requesting CON approval as an ODC for cardiac

PET scanning if and when such licensure is required by State law. Until required, the applicant will operate it as a service of its group practice. The project design and cost estimate allow for full compliance with ODC licensing regulations, is such licensure is ever sought.

B.II.D. DESCRIBE THE NEED TO CHANGE LOCATION OR REPLACE AN EXISTING FACILITY.

This is technically not applicable because the application is for a new provider. No replacement facility is involved.

However, the equipment concerned is changing its location. The reason for changing location is to move it closer to the patients who will use it, and to their specialists who must be on premises during a cardiac PET scans.

B.II.E. DESCRIBE THE ACQUISITION OF ANY ITEM OF MAJOR MEDICAL EQUIPMENT (AS DEFINED BY THE AGENCY RULES AND THE STATUTE) WHICH EXCEEDS A COST OF \$1.5 MILLION; AND/OR IS A MAGNETIC RESONANCE IMAGING SCANNER (MRI), POSITRON EMISSION TOMOGRAPHY (PET) SCANNER, EXTRACORPOREAL LITHOTRIPTER AND/OR LINEAR ACCELERATOR BY RESPONDING TO THE FOLLOWING:

- 1. For fixed site major medical equipment (not replacing existing equipment):
 - a. Describe the new equipment, including:
 - 1. Total Cost (As defined by Agency Rule);
 - 2. Expected Useful Life;
 - 3. List of clinical applications to be provided; and
 - 4. Documentation of FDA approval.
 - b. Provide current and proposed schedule of operations.
- 2. For mobile major medical equipment:
 - a. List all sites that will be served;
 - b. Provide current and/or proposed schedule of operations;
 - c. Provide the lease or contract cost;
 - d. Provide the fair market value of the equipment; and
 - e. List the owner for the equipment.
- 3. Indicate applicant's legal interest in equipment (e.g., purchase, lease, etc.) In the case of equipment purchase, include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

The cardiac PET scanner being relocated is a Siemens 2000 LS-EXCAT cardiac PET scanner system including the camera, workstation, software, water chiller unit, lead door, and in-lab furniture. The system's cost/value, as established by a third party evaluation, and as reflected in the applicant's purchase agreement, is \$325,000. It was installed at Gray in 2008 and its expected useful life is at least ten years. It will perform cardiac PET examinations for both perfusion and blockage evaluations. Its current hours of operation at Molecular Imaging in Gray are 7 am to 5 pm weekdays; this schedule will be maintained at its proposed new location in Kingsport. The applicant is purchasing the cardiac PET system. The executed conditional sales agreement is provided in the Attachments.

B.III.A. ATTACH A COPY OF THE PLOT PLAN OF THE SITE ON AN 8-1/2" X 11" SHEET OF WHITE PAPER WHICH MUST INCLUDE:

- 1. SIZE OF SITE (IN ACRES);
- 2. LOCATION OF STRUCTURE ON THE SITE;
- 3. LOCATION OF THE PROPOSED CONSTRUCTION; AND
- 4. NAMES OF STREETS, ROADS OR HIGHWAYS THAT CROSS OR BORDER THE SITE.

PLEASE NOTE THAT THE DRAWINGS DO NOT NEED TO BE DRAWN TO SCALE. PLOT PLANS ARE REQUIRED FOR ALL PROJECTS.

See Attachment B.III.A.

B.III.B.1. DESCRIBE THE RELATIONSHIP OF THE SITE TO PUBLIC TRANSPORTATION ROUTES, IF ANY, AND TO ANY HIGHWAY OR MAJOR ROAD DEVELOPMENTS IN THE AREA. DESCRIBE THE ACCESSIBILITY OF THE PROPOSED SITE TO PATIENTS/CLIENTS.

Kingsport is the largest community in Sullivan County. The project site on Meadowview Parkway in south Sullivan County is efficiently connected to all parts of its service area by Federal and State highways. I-26 connects the project site very quickly to I-81, the major east-west highway in that region. US Highway 11W also provides good east-west access. US Highways 58, 23, and 421 offer rapid access to southwest Virginia. Table Four below shows the average distances and drive times to principal cities in this project's service area.

	e Four: Mileage and Drive T ject at 3050 Meadowview Par		ort								
and Major (Communities in the Primary S	Service Area	, , , , , , , , , , , , , , , , , , , ,								
From Project to: County / State Distance Drive											
1. Abingdon	Washington (VA)	42.1 mi.	41 min.								
2. Johnson City	Washington	20.2 mi.	23 min.								
3. Rogersville	Hawkins	31.0 mi.	38 min.								
4. Greeneville	Greene	38.5 mi.	42 min.								
5. Wise	Wise (VA)	54.0 mi.	64 min.								
6. Gate City	Scott Co (VA)	11.6 mi.	17 min.								
7. Lebanon	Russell Co (VA)	47.4 mi.	67 min.								
8. Jonesville	Lee Co (VA)	47.3 mi.	57 min.								
9. Marion	Smyth Co (VA)	69.8 mi.	64 min.								

Source: Google Maps, April 2013.

B.IV. ATTACH A FLOOR PLAN DRAWING FOR THE FACILITY WHICH INCLUDES PATIENT CARE ROOMS (NOTING PRIVATE OR SEMI-PRIVATE), ANCILLARY AREAS, EQUIPMENT AREAS, ETC.

See attachment B.IV.

IV. FOR A HOME CARE ORGANIZATION, IDENTIFY

- 1. EXISTING SERVICE AREA (BY COUNTY);
- 2. PROPOSED SERVICE AREA (BY COUNTY);
- 3. A PARENT OR PRIMARY SERVICE PROVIDER;
- 4. EXISTING BRANCHES AND/OR SUB-UNITS; AND
- 5. PROPOSED BRANCHES AND/OR SUBUNITS.

Not applicable. The application is not for a home care organization.

C(I) NEED

- C(I).1. DESCRIBE THE RELATIONSHIP OF THIS PROPOSAL TO THE IMPLEMENTATION OF THE STATE HEALTH PLAN AND TENNESSEE'S HEALTH: GUIDELINES FOR GROWTH.
- A. PLEASE PROVIDE A RESPONSE TO EACH CRITERION AND STANDARD IN CON CATEGORIES THAT ARE APPLICABLE TO THE PROPOSED PROJECT. DO NOT PROVIDE RESPONSES TO GENERAL CRITERIA AND STANDARDS (PAGES 6-9) HERE.
- B. APPLICATIONS THAT INCLUDE A CHANGE OF SITE FOR A HEALTH CARE INSTITUTION, PROVIDE A RESPONSE TO GENERAL CRITERION AND STANDARDS (4)(a-c).

Project-Specific Review Criteria: PET Scanners

The State Health Plan contains CON review criteria for PET scanners. The applicant believes that responses to those criteria should not be required for this project. They were intended to guide review of proposed new PET units in a service area, i.e., projects in which an additional PET is proposed for an area, or in which a prior approved PET is proposing a relocation that will result in a new service area.

Neither factor is present in this project. This project is to acquire an existing cardiac PET system, not to add a system to the area. At its proposed new location, this cardiac PET system will serve only counties that it is already serving at its current location. The ODC already received prior CON approval to serve those counties, and has done so for more than five years. A re-evaluation of this service under the PET Guidelines would not be meaningful for this particular change of ownership and location. The applicant requests that responses to these criteria not be required.

WELLMONT CARDIOLOGY SERVICES CN1304-013

RESPONSES TO CON STANDARDS AND CRITERIA FOR POSITRON EMISSION TOMOGRAPHY SERVICES (PET SERVICES)

SUPPLEMENTAL

April 29, 2013 4:20 pm

PET REVIEW CRITERIA 2009 STATE HEALTH PLAN

Introduction

The applicant is addressing below the CON review standards and criteria ("the criteria") adopted in the 2009 State Health Plan.

However, as noted in some of the responses, "need" criteria do not seem applicable to a change of site of an authorized and operational PET unit, when its new site is in the same service area for which PET service was approved in 2007.

That is clear from the language of the need sections, which state that they apply to "new" or "additional" units or services. There are two PET systems lawfully in operation in the area today; and if both companion CON applications to relocate them are approved, the same two PET systems will continue to serve the originally approved area, but from two more accessible locations within that area.

Following this page is a copy of the PET Standards and Criteria from the 2009 State Health Plan.

Following that document are the applicant's responses to them, numbered to correspond to the State Health Plan document.

APPENDIX A. Revised and Updated Standards and Criteria for Positron Emission Tomography (PET) services



STATE OF TENNESSEE

STATE HEALTH PLAN CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

POSITRON EMISSION TOMOGRAPHY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Positron Emission Tomography (PET) services. Existing providers of PET services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for PET services.

These standards and criteria are effective immediately as of November 18, 2009, the date of approval and adoption by the governor of the State Health Plan. Applications to provide PET services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Positron Emission Tomography (PET): A noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body (source: The Centers for Medicare and Medicaid Services). PET differs from other nuclear medicine modalities in the type of radiation emitted and in the type of scanner required to detect it. By measuring the distributions of certain radiotracers in the body some time after they have been administered, PET can be used to diagnose physical abnormalities and to study body functions in normal subjects.

PET Unit: Diagnostic equipment (often referred to as a "scanner") that uses a positron camera (tomograph) to produce cross-sectional tomographic images (this process is often referred to as a "scan"). The images are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-(F-18) Fluoro-D-Glucose (FDG) which are administered intravenously to the patient. The radioactive tracers may be

produced on-site, e.g. with a cyclotron, or may be ordered from commercial distributors. As a result, factors such as equipment cost, geographic distribution and availability of distributors, and other related factors (regulatory compliance/certification) should be considered by the Agency in its review of all PET applications.

First developed in the 1970s, initial PET scanners were dedicated machines performing only that service. PET scanners can be either fixed (stationary) or mobile. Current technological adaptations include hybrid machines, such as combined PET-CT (computed tomography) scanners that are capable of performing a variety of nuclear medicine studies.

PET Procedure: A PET diagnostic scan or combination of scans performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition.

Stationary PET Unit: A non-moveable PET unit housed at a single permanent location.

Mobile PET Unit: A PET unit and transporting equipment that is moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the Continental United States.

Capacity: The measure of the maximum number of PET scans per PET unit per year based upon the type of PET equipment to be used (i.e., stationary or mobile).

Stationary PET Unit Capacity: Total capacity of a stationary PET unit is 2,000 procedures per year and is based upon a daily operating efficiency of eight procedures per day x 250 days of operation per year. The optimal efficiency for a stationary PET unit is 80 percent of total capacity, or 1,600 procedures per year.

Mobile PET Unit Capacity: Total capacity of a mobile PET scanner is 400 annual procedures per day of operation per week and is based upon a daily operating efficiency of at least eight (8) procedures per day x number of days in operation per week x approximately 50 weeks per year. The optimal efficiency of a mobile PET unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 320 procedures per year, or 80 percent of total capacity.

PET Unit Service Area: The counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide PET unit services, including, but not limited to, oncology and cardiology diagnostic and treatment services, and in which at least 75% of its service recipients reside. A PET unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of PET units needed in a given service area. The estimate is based upon an optimal efficiency of 1,600 procedures per year for a stationary PET unit and an optimal efficiency of 320 annual procedures per day of operation per week for a mobile PET unit, and the quantitative estimate of the number

of patients who potentially could benefit from PET diagnostic services, especially those patients pertaining to the following categories:

- those patients where the use of PET unit services is essential to the diagnosis, treatment, or surveillance of cancer, including, but not limited to, diagnosis codes approved by the Centers for Medicare and Medicaid Services (CMS);
- those patients who are either non-emergent candidates for open heart surgery or therapeutic cardiac catheterization procedures;
- those patients with a diagnosis of partial complex epilepsy for whom surgical intervention is being considered; and
- any other patient population that may benefit from the accessibility to stationary or mobile PET unit services as a result of expanded clinical applications and changes in the reimbursement of PET service by third party payors, including those pertaining to programs administered by the CMS.

In addition to the above determinants of service area capacity, applicants should consider demographic patterns, including the results of estimates of population health risk factors and population-based cancer, heart disease, or other applicable clinical incidence rates. The data should be consistent with data prepared by the Tennessee Department of Health. Applicants should also document the extent, if any, of diagnostic oncology, cardiac and neurological medical services in the proposed service area in its determination of the need for PET unit services.

Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed

service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

- 3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.
- 4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.
- 5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelvementh period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

- 6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.
 - b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
 - c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

- d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.
- e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.
- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.
- 7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.
- 8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;
 - c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

SUPPLEMENTAL

April 29, 2013 4:20 pm

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Responses to the Criteria

Note: For brevity, the CON PET criteria are paraphrased below in bold letters. Also, the applicant has added subparts A, B, etc. to the numbered CON criteria when responding to multiple components of some criteria.

1A. Projected Utilization--1,000 procedures in Year One; 1,600 in Year Two

The application substantially complies with this criterion, in projecting 1,500 procedures in each of the first two years. The applicant expects to perform 1,600 procedures in the third year.

1B. Demographic Data--Population based health factors and ICD-9 level projections

The application projects population growth, and utilization by ICD-9 codes, as required by HSDA staff and rules. But the application does not base its projected utilization or need, or derive its ICD-9 projections, from population-based health factors.

The need for the project, and its future utilization, rely only on the current number of patients who are actually being treated in the applicant's practice today. That is not a speculative number. Approximately 1,500 current WCS patients need better access to cardiac PET service than has been available since 2007, or will be available when the only other provider of that service moves even farther away to the east.

2A. Applicants "applying for a proposed new PET unit" should document its accessibility to 75% of the service area population.

Not applicable because the applicant is not proposing a new PET unit or a new service area. Also, the criterion does not define "accessibility". However, Table Four on page 18 of the application provided drive time data demonstrating accessibility to selected counties in both Tennessee and Virginia. Following is additional information on its accessibility to its Tennessee service area counties other than its own home county.

Table PET-1: Distance & Drive Time										
from Project in Kingsport, Sullivan County, to TN Primary Service Area Counties										
County / City	Driving Distance	Drive Time								
1. Carter / Elizabethton	29.2 miles	34 minutes								
2. Greene / Greeneville	38.5 miles	42 minutes								
3. Hawkins / Rogersville	31.0 miles	38 minutes								
4. Johnson / Mountain City	68.6 miles	76 minutes								
5. Unicoi / Erwin	34.5 miles	36 minutes								
6. Washington / Johnson City	20.2 miles	23 minutes								
7. Cocke / Newport	68.2 miles	67 minutes								
8. Hamblen / Morristown	55.5 miles	54 minutes								
9. Hancock / Sneedville	53.9 miles	78 minutes								

Source: Google Maps

SUPPLEMENTAL

April 29, 2013 4:20 pm

2B. Identify PET unit locations, capacity, and utilization in non-Tennessee counties in the service area, and discuss project impact on them.

The Virginia service area counties are Wise, Scott, Russell, Lee, and Smythe. The only hospital of significant size in that area appears to be Johnson Memorial Medical Center in Abingdon, which has mobile PET service and is located 42 miles from Kingsport. The applicant does not know its schedule or its utilization, but believes that it is not equipped to perform cardiac PET scans. The applicant knows of no other PET service in those five counties.

However, this project would not adversely impact any Virginia PET, because the applicant's utilization will consist exclusively of its own existing patients who have sought care from WCS cardiologists and are now obtaining diagnostic care within the WCS offices. In addition, in the unlikely event that the Abingdon mobile service were to become equipped for cardiac PET scans, it would be prohibitively difficult for Kingsport WCS cardiologists to accompany high volumes of Tennessee patients 42 miles away in Abingdon.

3. Document that alternate shared services and lower cost technology are known to be less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

For the large number of patients at WCS who need this service, there is no shared service option that is accessible to WCS physicians who must be on-site to supervise the procedures. The existing Gray facility made a good attempt at such sharing; but its under-utilization over the past five years has shown that this service needs to be available within, rather than between, the two large medical referral cities in this region (Kingsport and Johnson City).

There is no lower cost technology that can provide the diagnostic information cardiac PET provides, for the type of patient who is appropriate for it.

The relocation of this existing PET unit to WCS's own office at Kingsport will help WCS physicians improve the quality and continuity of care by having on-site control of its operation. It will also lower the cost of care by frequently ruling out the need for, or the feasibility of, subsequent cardiac catheterization and surgical procedures. One academic study provided in the Attachments to the application quantified a substantial "downstream" savings in overall healthcare costs, from substituting cardiac PET for SPECT in appropriate patient populations.

4. (This criterion is not applicable because it pertains only to a proposed new mobile PET.)

5A. Need for "one additional stationary PET unit in an area" is likely if the utilization of existing PET providers was at or above 80% of their total capacity as reported to HSDA most recently.

The criterion is not applicable because the applicant is not requesting an additional unit.

Table PET-2 on the next page provides the requested data. The applicant notes the following in response to the standards for optimal average areawide utilization (1,600 procedures for fixed units; 320 procedures per each operational day per week for mobile units).

- The applicant has 1,800 patients a year needing this kind of diagnostic service in Kingsport; and 1,500 of them do not have access to it. The need is so large that daily access to this service Monday-Friday is needed.
- The definitions in the PET criteria state that patients should have reasonable access for service area residents. That should mean that physician and patient inaccessibility to a service location are to be weighed against areawide utilization standards where relevant.
- The accessible mobile unit at Holston Valley Medical Center (HVMC) is unable to schedule any more WCS patients than the 300 it already serves. The mobile unit standard is 320 annual procedures per day of service each week. The unit is docked at HVMC three days a week, so its standard is 960 annual procedures at that location. It is performing 1,677 procedures annually at HVMC. That is almost double the CON standard. It is in service five days a week already and so no more capacity is available on that mobile unit.
- All mobile PET units in the Tennessee service area are utilized at a group average of 6.8 procedures per day (9 days of service a week X 50 weeks per year = 450 available days; 3,036 procedures on mobiles / 450 days = 6.8 procedures per day of service). That is 85% of total capacity (6.8 / 8 patients capacity), well above the 80% CON standard.
- The applicant believes that the mobile PET coming to Indian Path Medical Center in Kingsport, and the fixed PET at Johnson City Medical Center in Sullivan County, do not perform cardiac PET studies. That mobile is available only one day a week; so even were it able and willing to perform cardiac studies, it could not accommodate the 1,500 additional patients per year that WCS is seeking to have served. Johnson City Medical Center is not fully utilized; but even were it able and willing to perform cardiac PET scans, it is at a location inaccessible to almost all WCS physicians.
- The fixed PET at Gray is seriously underutilized, at approximately 17% of capacity (334 procedures / 2000 procedure capacity) By taking it from LifeScan at Gray to WCS at Kingsport, where it will serve 1,500 currently underserved WCS patients, the utilization of that unit will be increased to 449% of its 2012 utilization, without taking a single cardiac PET patient from the utilization of any PET in the area.

County	Provider	Mobile or Fixed	Days Per Week	Annual Procedures
Greene	Laughlin Memorial Hospital	Mobile	1	351
Hamblen	Morristown-Hamblen Hospital	Mobile	2	405
Sullivan	Holston Valley Regl Med Cntr	Mobile	3	1,677
	Bristol Regl Medical Center	Mobile	2	460
	Indian Path Medical Center	Mobile	1	143
	Subtotal, Mobiles	j j	9	3,030
Washington	Johnson City Medical Center	Fixed		1,234
_	Molecular Imaging (LifeScan)	Fixed (2)		623*
	Total, All Units			4,893

Source: HSDA Registry 4/24/13. *Molecular procedures were 623 to Tennessee patients but 668 to all patients. Provider report to Registry will be corrected by Molecular under separate cover. Originally reported figure used here for consistency of source. Difference is insignificant for purposes of this project analysis.

5B. Applicants for a stationary unit should perform at least 1,000 and 1,600 procedures per year in the first two years, respectively.

This repeats criterion 1. The application substantially complies with this criterion, in projecting 1,500 procedures in each of the first two years. The applicant expects to perform 1,600 procedures in the third year.

6a. The PET unit must be FDA-certified for clinical luse.

Documentation of certification was submitted in the original application's Attachments.

6b. The PET's physical environment must conform to applicable Federal standards, manufacturer's specifications, and licensing requirements.

Compliance with applicable standards and regulations is assured by the architect's letter attesting to intended compliance. That was provided in the Attachments.

6c. The applicant should demonstrate how emergencies will be managed in conformity with accepted medical practice.

Please see the applicant's draft protocols for emergency response, attached at the end of this response section.

6d. The applicant should establish protocols assuring that procedures are medically necessary and not unnecessarily duplicative.

Please see the applicant's draft protocols for that, attached at the end of this response section.

6e. Medical Direction

The Medical Director for the service (and for the ODC if licensure is required) has not yet been identified. However, a job description for the position is attached, to document compliance with the criteria. On April 26, the applicant submitted the resumes of the WCS cardiologists who will be most active in this service. The resumes document that they do, and will, comply with the applicable standards of criterion 6e. They are licensed physicians, Boarded cardiologists with certification in nuclear cardiology, approved to oversee handling of radiopharmaceuticals and medical isotopes, and qualified and experienced in interpreting cardiac nuclear medicine studies, which is what PET is.

One aspect of the standards is ambiguous to the applicant: the reference to "Board Certification in Nuclear Medicine or Diagnostic Radiology". For decades across the United States, cardiologists certified in Nuclear Cardiology--which these WCS physicians are--have been supervising and interpreting nuclear medicine studies such as SPECT and PET. That is what will happen in this project. The applicant believes that the standards should be assumed to include such specialists because that is an industry standard for cardiac PET.

6f. Emergency transfer agreement; Medical Director Required to Have Staff Privileges

The practice will seek a transfer agreement with Holston Valley Medical Center if licensed as an ODC. That is not necessary as a medical practice; all the WCS physicians at this location have admitting privileges and are on staff at that hospital. Practices do not sign transfer agreements with hospitals, to the best of the applicant's knowledge.

Upon contracting with a Medical Director, that person's privileges at HVMC will be required by contract.

7. Submission of data to HSDA

The applicant commits to comply with the requirement for timely submission of data to the HSDA for the Equipment Registry.

SUPPLEMENTAL April 29, 2013 4:20 pm

Factors for Special Consideration

8a. Service to Medically Underserved Areas

WCS's total service area covers large numbers of medically underserved areas in Tennessee and in southwest Virginia. Attached to illustrate that are several listings of those areas at the county/census tract level. More can be provided if required; these are illustrative.

8b. Higher than Average Rates of Heart Disease

The applicant is not claiming this special circumstance at this time. It is neither a new service nor an additional unit for the area, so justification of this type is not needed.

8c. Safety Net Hospital; Comprehensive Cancer Program

WCS, the applicant, is wholly owned by Wellmont Health System, whose tertiary referral hospital in Kingsport--Holston Valley Medical Center--is a practice site for WCS physicians. That facility is designated by TennCare as a Safety Net Hospital. It is also designated as a Comprehensive Cancer Diagnosis and Treatment Program location.

8d. TennCare and Medicare Participation

As stated in the original application, the applicant contracts with all area TennCare MCO's and with Medicare. Please see the application, pages 4 and 45.

WELLMONT CARDIOLOGY SERVICES CN1304-013

RESPONSES TO CON STANDARDS AND CRITERIA FOR OUTPATIENT DIAGNOSTIC CENTERS (ODC)

4:20 pm

OUTPATIENT DIAGNOSTIC CENTER REVIEW CRITERIA TENNESSEE GUIDELINES FOR GROWTH (2000)

1. The need for outpatient diagnostic <u>services</u> shall be determined on a county by county basis (with data presented for contiguous counties for comparative purposes) and should be projected four years into the future using available population figures.

The county where the project is located is Sullivan County. Contiguous to Sullivan County are Hawkins, Washington, Carter, and Johnson Counties. These five are only half of the Tennessee primary service area counties to be served by this project, and none of the Virginia service area counties; so this criterion's methodology for analysis appears to be not useful or logical for evaluating need for this project. The basis for the need for this project has been discussed in several other sections of the application, especially B.II.C. That basis is the actual number of patients currently being seen by the applicant's physicians, patients who are currently in need of the utilization projected for this project.

Moreover, there is no publicly available data on either the number, or the incidence rates, of cardiac PET studies within reported totals of PET studies; so it is not possible to do a population-based projection of need for this service. SPECT data is not useful, because SPECT utilization takes place in physician offices as well as hospitals, and is largely unreported for analysis. Even hospitals report only total nuclear medicine studies rather than SPECT nuclear medicine studies themselves. However, to provide types of information requested in the criterion, the applicant submits the following.

Table ODC-1 below shows these five counties' current (2013) and projected (2017) populations. Table ODC-2 shows the identifiable actual plus potential cardiac PET scans needed by residents of the five counties, according to Joint Annual Reports of the area's only dedicated cardiac PET provider, and projections from WCS records. No information is available on what additional cardiac PET scans might have been provided by other fixed or mobile PET units operating in these five counties, because hospital JAR data does not identify cardiac PET studies separately from oncology or neurology studies.

County	By Molecular	By HVMC	Scans In Five-County Ar WCS Unmet Need	Total
Sullivan	40	80	402	522
Carter	119	8	39	166
Hawkins	5	24	120	149
Johnson	21	2.	12	35
	330	25	126	481
Washington Total	515	139	699	1,353

Sources: Molecular Imaging Alliance records; HVMC data projected by applying WCS patient origin data to WCS patients who need, but are unable, to obtain the service on the HVMC mobile.

Table ODC-2: Projected Population Change in Five-County Area										
County	2013 Population	2017 Population (% Change)								
Sullivan	62,939	64,809								
Carter	22,330	23,184								
Hawkins	22,457	23,925								
Johnson	7,518	7,940								
Washington	43,059	45,640								
Total	158,303	165,498 (+4.6%)								

Source: TDH Population projections Feb. 2008.

2. Approval of outpatient diagnostic services will be made only when it is demonstrated that existing services in the applicant's geographical service area are not adequate and/or there are special circumstances which require additional services.

This criterion is met because physical accessibility to this important service in Gray is not adequate currently for WCS cardiologists, and because the service provider is planning to relocate almost twice as far away (20.6 miles vs. 10.6 miles currently), making access completely unfeasible for Kingsport patients who choose to use Kingsport cardiologists. This will leave WCS with only one known option for this service in Kingsport--use of the Wellmont Holston Valley Medical Center mobile PET unit. That unit currently restricts the number of cardiac PET scans that be scheduled. No more than 300 per year can be served. This is less than 17% of the total number of WCS patients that WCS would like to schedule for this test:

300 served + 1,500 unserved = 1,800 total patients needing the study 300 served / 1,800 needing to be served = 16.7% of need being met

4:20 pm

To increase its accessibility to Kingsport cardiologists, so that it can serve many more WCS patients who need it, WCS needs to acquire Molecular's second cardiac PET system and move it north into Kingsport.

3. Any special needs and circumstances:

a. The needs of both medical and outpatient diagnostic facilities and services must be analyzed.

The need addressed by the application is for certain large-body-mass patients in WCS offices (currently 1500 per year) to have access to a cardiac PET scan in place of, or to supplement, the SPECT tests that are their only other option in Kingsport. They cannot do so now, because the region's only cardiac PET in Gray is too far away to allow WCS physicians to routinely go there to supervise their patients' tests. Now that the Gray facility is moving almost twice as far away from Kingsport, and is willing to take with it only one of the two PET units it operates in Gray, it is logical for WCS to acquire the other existing unit and move it to Kingsport to eliminate accessibility issues for a large WCS patient population.

There are no other medical offices, or ODC's, that will be affected by the project. But the project would clearly improve these particular patients' healthcare and the total costs of their care (as explained in Section B.II.B of the application).

b. Other special needs and circumstances which might be pertinent must be analyzed.

No special needs and circumstances have been identified, other those identified above and in other parts of this application.

- c. The applicant must provide evidence that the proposed diagnostic outpatient services will meet the needs of the potential clientele to be served.
 - 1. The applicant must demonstrate how emergencies within the outpatient diagnostic facility will be managed in accordance with accepted medical practice.

SUPPLEMENTAL

April 29, 2013 4:20 pm

The proposed ODC will be located in The Heart Center office building, within a group practice of cardiac care specialists who have admitting privileges at nearby Holston Valley Medical Center. Any of these physicians can send an emergency patient to the hospital Emergency Department, and/or admit the patient. Initial "first responder" emergency care will be provided by physicians and other WCS health professionals on-site, while emergency transport is on its way. No transfer agreement is necessary. If an ODC is required to be formed to offer this service at WCS, that ODC would seek an emergency transfer agreement with Holston Valley Medical Center in Kingsport, just minutes away by ambulance.

Please also see the draft emergency response protocols attached in the next section, in response to Criterion 6d of the PET CON review standards and criteria.

2. The applicant must establish protocols that will assure that all clinical procedures performed are medically necessary and will not unnecessarily duplicate other services.

Please see the draft protocols attached in the next section, in response to criterion 6d of the PET CON review standards and criteria.

The Framework for Tennessee's Comprehensive State Health Plan

Five Principles for Achieving Better Health

The following Five Principles for Achieving Better Health serve as the basic framework for the State Health Plan. After each principle, the applicant states how this CON application supports the principle, if applicable.

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans. Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

This project reflects a cooperative effort by the applicant and the owner of the Molecular Imaging Alliance ODC in Gray, to "subdivide" the two underutilized PET units at Gray, and to move them closer to the region's two largest concentrations of patients and cardiologists needing that service. The result will be to increase use of this diagnostic modality, to gain cost savings and improved diagnostic information that can reduce some costs of acute cardiac care.

2. Access to Care

Every citizen should have reasonable access to health care.

Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

Geography has been a barrier to optimal use of cardiac PET scanning. It is located miles outside the medical centers of the service area, making it less accessible for patients and physicians and limiting its use. The project will address that issue, improving access over what it is today.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system. The State Health Plan should

work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.

This is an opportunity for the State regulatory system to assist providers in making a needed service more accessible, so that its technology can be more completely and efficiently utilized.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

Bringing this PET system into The Heart Center, under the medical direction of Wellmont Cardiology Services, will place it in one of Tennessee's most quality-controlled acute care provider systems. Wellmont has been widely recognized and nationally ranked for its cardiac services. Having on-site availability of this technology will allow WCS specialists to acquire superior diagnostic data, with which they can make improved and more cost-effective decisions on subsequent care of the cardiac patient.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

The applicant's parent health system is deeply engaged in health profession training programs to increase the supply of competent practitioners at all levels of care.

C(I).2. DESCRIBE THE RELATIONSHIP OF THIS PROJECT TO THE APPLICANT'S LONG-RANGE DEVELOPMENT PLANS, IF ANY.

The applicant is not a hospital and does not prepare its own long-range campus or development plan.

C(I).3. IDENTIFY THE PROPOSED SERVICE AREA AND JUSTIFY THE REASONABLENESS OF THAT PROPOSED AREA. SUBMIT A COUNTY-LEVEL MAP INCLUDING THE STATE OF TENNESSEE CLEARLY MARKED TO REFLECT THE SERVICE AREA. PLEASE SUBMIT THE MAP ON A 8-1/2" X 11" SHEET OF WHITE PAPER MARKED ONLY WITH INK DETECTABLE BY A STANDARD PHOTOCOPIER (I.E., NO HIGHLIGHTERS, PENCILS, ETC.).

A service area map and a map showing the location of the service within the State of Tennessee are provided as Attachments C, Need--3 at the back of the application.

The cardiac PET service area will reflect the patient origin of WCS patients in CY2012. That area will include the counties that this PET unit has been serving in Gray, since its ODC opened more than five years ago. Table Six on the next page shows the CY2012 primary service area counties for the practice, and projects county-level cardiac PET patient origin for the primary service area in Years One and Two of the project.

Approximately 84% of the cardiac PET patients will come from ten upper East Tennessee and southwest Virginia counties, many of whose residents look to the Wellmont system for their cardiac care. As might be expected, more than a third will come from the two most urbanized counties in this group, where Kingsport and Johnson City are located.

1:15 pm

Table Six: Patient Origin Wellmont Cardiology Services & Cardiac PET Scans CY2012 / CY2014-CY2015 CY2015 Cumulative CY2014 wcs Cardiac Cardiac Percent of **Patients** Percent of **PET Scans PET Scans** Total Total CY2012 County 402.2 402.2 26.8% 12,085 26.8% Sullivan 182.3 182.3 12.2% 39.0% 5,478 Washington (VA) 125.9 47.4% 125.9 3,784 8.4% Washington 120.0 120.0 8.0% 55.4% 3,607 Hawkins 109.3 109.3 62.6% 7.3% 3,283 Greene 100.4 100.0 69.3% 3,018 6.7% Wise (VA) 61.0 61.1 4.1% 73.4% 1,837 Scott (VA) 54.0 54.3 3.6% 77.0% 1,631 Russell (VA) 54.0 80.6% 53.6 3.6% 1,610 Lee (VA) 52.0 3.5% 84.1% 52.5 1,577 Smyth (VA) 939.7 939.7 84.1% 37,910 Primary Service Area Subtotal 560.3 560.3 7,163 15.9% 69 Other Counties in 5 States <3% of Grand Total 1,500.0 1,500.0 100.0% 45,073 Grand Total

Source: WCS patient origin from practice record; cardiac pet projections by WCS management.

C(I).4.A DESCRIBE THE DEMOGRAPHICS OF THE POPULATION TO BE SERVED BY THIS PROPOSAL.

Table Seven, following this page, provides the demographic profile for the four Tennessee counties in this project's primary service area. Basically, area residents are somewhat older and lower income than the State average.

The counties in the primary service area (all in Tennessee) have a median age of 41.9 compared to the State median age of 37.8; and 17.6% of area residents are elderly compared to 13.8% Statewide. In addition, the service area's elderly population is projected to increase 9.1% in size over the next four years. The aging of the population will continue to increase the need for high-quality, accessible, affordable cardiac care in this area. This project will support all three goals.

The service area's median income of \$38,945 is 10% lower than the State average; and more of the residents live below poverty level (18.1%) than the State average of 16.5%. The service area's TennCare population is 17.7% of all residents, compared to 19% Statewide. The project will be part of the not-for-profit Wellmont Health System, which is very accessible to low-income residents of the service area. A large majority (70%) of patients served by this project will be Medicare or Medicaid/TennCare enrollees.

2013 APR 15 PM 3: 08

Table Seven: Demographic Characteristics of Tennessee Primary Service Counties Wellmont Cardiology Services & Cardiac PET Service 2013-2017											
Demographic	Sullivan County	Washington County	Hawkins County	Greene County	PRIMARY SERVICE AREA	STATE OF TENNESSEE					
Median Age-2010 US Census	43.6	39.3	42.1	42.6	41.9	37.8					
Total Population-2013	154,387	120,136	60,131	68,390	403,044	6,361,070					
Total Population-2017	154,946	123,276	61,865	69,636	409,723	6,575,165					
Total Population-% Change 2013 to 2017	0.4%	2.6%	2.9%	1.8%	1.7%	3.4%					
Age 65+ Population-2013	29,471	19,303	10,211	12,146	71,131	878,496					
% of Total Population	19.1%	16.1%	17.0%	17.8%	17.6%	13.8%					
Age 65+ Population-2017	31,683	21,430	11,333	13,173	77,619	987,074					
% of Population	20.4%	17.4%	18.3%	18.9%	18.9%	15.0%					
Age 65+ Population- % Change 2013-2017	7.5%	11.0%	11.0%	8.5%	9.1%	12.4%					
Median Household Income	\$40,572	\$42,104	\$36,795	\$36,310	\$38,945	\$43,314					
TennCare Enrollees (12/12)	27,451	19,002	11,903	12,877	71,233	1,205,480					
Percent of 2012 Population Enrolled in TennCare	17.8%	15.8%	19.8%	18.8%	17.7%	19.0%					
Persons Below Poverty Level (2012)	25,474	20,784	10,162	14,772	71,192	1,049,57					
Persons Below Poverty Level As % of Population (US Census)	16.5%	17.3%	16.9%	21.6%	18.1%	16.5%					

Sources: TDH Population Projections, Feb. 2008; U.S. Census QuickFacts and FactFinder2; TennCare Bureau. PSA data is unweighted average or total of county data. NR means not reported in U.S. Census source document.

C(I).4.B. DESCRIBE THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION, INCLUDING HEALTH DISPARITIES, THE ACCESSIBILITY TO CONSUMERS, PARTICULARLY THE ELDERLY, WOMEN, RACIAL AND ETHNIC MINORITIES, AND LOW-INCOME GROUPS. DOCUMENT HOW THE BUSINESS PLANS OF THE FACILITY WILL TAKE INTO CONSIDERATION THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION.

The applicant group practice is dedicated to the diagnosis, care, and prevention of cardiovascular disease. Its cardiac PET service will be recommended to a subset of patients with indications of cardiovascular disease. These will predominantly be elderly persons (age 65+), who account for almost 69% of this practice's nuclear medicine studies (cardiac PET scanning is a nuclear medicine procedure). This age group has complete accessibility to this practice. The practice also takes TennCare and provides charity care. As part of the non-profit Wellmont Health System, WCS is accessible to all patients in the community.

C(I).5. DESCRIBE THE EXISTING OR CERTIFIED SERVICES, INCLUDING APPROVED BUT UNIMPLEMENTED CON'S, OF SIMILAR INSTITUTIONS IN THE SERVICE AREA. INCLUDE UTILIZATION AND/OR OCCUPANCY TRENDS FOR EACH OF THE MOST RECENT THREE YEARS OF DATA AVAILABLE FOR THIS TYPE OF PROJECT. BE CERTAIN TO LIST EACH INSTITUTION AND ITS UTILIZATION AND/OR OCCUPANCY INDIVIDUALLY. INPATIENT BED PROJECTS MUST INCLUDE THE FOLLOWING DATA: ADMISSIONS OR DISCHARGES, PATIENT DAYS, AND OCCUPANCY. OTHER PROJECTS SHOULD USE THE MOST APPROPRIATE MEASURES, E.G., CASES, PROCEDURES, VISITS, ADMISSIONS, ETC.

There is only one cardiac PET service in Upper East Tennessee. It is at the Molecular Imaging Alliance ODC in Gray (northwest Washington County). Table Eight below shows its utilization in 2009-2012. Its growth has been exceptionally strong despite its remote location midway between the region's two largest medical care centers. Over the period 2009-2012, utilization of the service increased more than 17% per year (compound annual growth rate or CAGR).

Table Eight: Utilization of Molecular Imaging Alliance Cardiac PET Service 2009-2012										
	2009	2010	2011	2012						
Procedures	411	342	514	668						
% Annual Change		- 16.8%	+50.3%	+30.0%						
Numeric Annual Change		-69	+172	+154						
% Change 2009-2012			(c)###	+62.5%						
Numeric Change 2009-12	24			+257						
Compound Annual Growth Rate 2009-2012				>17%						

Source: HSDA Registry 2009-11; Molecular Imaging Alliance records, 2012.

																			68	3													C
Total Gross	\$1 375 036 00	\$1 978 760 00	\$1.815.432.00	\$1.483.770.00	\$1,534,500.00	\$987.000.00	\$1,313,875.00	\$1,808,573.00	\$2,067,596.00	\$1,840,351.00	\$2,080,050.00	\$2,105,911.00	\$5,626,711.00	\$6,154,683.00	\$6,636,461.00	\$7,542,662.00	\$931,955.00	\$1,061,218.00	\$1,000,842.00		\$14,209,376.00	\$12,136,169.00	\$11,506,728.00	\$10,275,190.00	\$1,336,879.00	\$587,344.00	\$1,623,309.46	\$1,139,661.00	\$27,082,053.00	\$24,695,525.00	\$25,976,697.46	\$25,558,058.00	
Total Procedures	436	456	430	351	341	296	317	405	464	435	466	460	1263	1381	1501	1677	138	154	133	143	2121	1769	1542	1234	411	342	514	623	5174	4833	4903	4893	
Mobile Days Used	1 dav/week	2 davs/week	2 days/week	1 day/week	2 days/week	3 days/week	2 days/week	2 days/week	2 days/week	2 days/week	2 days/week	2 days/week	3 days/week	3 days/week	3 days/week	3 days/week	1 day/week	1 day/week	1 day/week	1 day/week	0	0	0	0	0	0	0	0					
Mobile?	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Mobile (Part)	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed					
Number of	1	1	1	H	1	1	н	1	1	1	1	1	1	Н	₽	1	1	1	Ħ	1	1	1	1	1	2	2	2	2	00	œ	œ	00	
Year	2009	2010	2011	2012	2009	2010	2011	2012	2009	2010	2011	2012	2009	2010	2011	2012	2009	2010	2011	2012	2009	2010	2011	2012	2009	2010	2011	2012					
Provider	Laughlin Memorial Hospital, Inc.	Morristown-Hamblen Hospital	Morristown-Hamblen Hospital	Morristown-Hamblen Hospital	Morristown-Hamblen Hospital	Bristol Regional Medical Center	Holston Valley Medical Center	Indian Path Medical Center	Johnson City Medical Center	LifeScan Tennessee, LLC	LifeScan Tennessee, LLC	LifeScan Tennessee, LLC	LifeScan Tennessee, LLC	2009 Service Area Total	2010 Service Area Total	2011 Service Area Total	2012 Service Area Total																
Provider Type	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	HOSP	ODC	ODC	ODC	ODC					
County	Greene	Greene	Greene	Greene	Hamblen	Hamblen	Hamblen	Hamblen	Sullivan	Sullivan	Sullivan	Sullivan	Sullivan	Sullivan	Sullivan	Sullivan	Sullivan	Sullivan	• .	Sullivan	Washington	Washington	Washington	Washington	Washington	Washington	Washington	Washington					

Medical Equipment Registry - 4/24/2013

SUPPLEMENTAL April 29, 2013 4:20 pm

1:15 pm

PROVIDE APPLICABLE UTILIZATION AND/OR OCCUPANCY C(I).6. STATISTICS FOR YOUR INSTITUTION FOR EACH OF THE PAST THREE (3) YEARS AND THE PROJECTED ANNUAL UTILIZATION FOR EACH OF THE THE PROJECT. COMPLETION FOLLOWING TWO (2)YEARS REGARDING THE **DETAILS PROVIDE** THE ADDITIONALLY. THE UTILIZATION. **PROJECT** USED TO METHODOLOGY MUST INCLUDE DETAILED CALCULATIONS OR METHODOLOGY DOCUMENTATION FROM REFERRAL SOURCES, AND IDENTIFICATION OF ALL ASSUMPTIONS.

The applicant has projected utilization of its cardiac PET service based on two factors. First, the "conversion" of some of WCS's and the Wellmont hospitals' SPECT studies to cardiac PET studies—i.e, ordering a PET study instead of a SPECT study. This will be done in approximately 7-10% of WCS's current volumes of 30 to 40 SPECT studies per day, 250 days per year. The number chosen for projection purposes was 3 cardiac PET scans per day, which is 750 scans per year.

Second, utilization was also projected in the performance of cardiac PET studies subsequent to SPECT studies whose results were clinically equivocal or inconclusive. This too is projected at 7%-10% of all the SPECT tests, resulting in an additional demand for 3 cardiac PET scans per day, or another 750 per year.

The total projection for the first two years is therefore 1,500 cardiac PET procedures per year in CY2014 and CY2015.

These SPECT patients would have been scheduled for cardiac PET at the Holston Valley Medical Center mobile PET, but for the fact that it is so highly utilized by cancer patients that no more than 300 WCS cardiology procedures per year are allowed to be scheduled--resulting in a waiting list of two months at the time of this application. Most patients are having to go ahead with SPECT to progress with their medical care. Although WCS tried initially to use the Gray cardiac PET scanners, that required its cardiologists to be at Gray for hours each day, during which time they could not be providing needed care for patients at their practice office. With a PET at the practice office, supervision (i.e., being onsite and available immediately in case of an emergency) will enable the cardiologists to be productive in the care of other patients at the same time.

- C(II)1. PROVIDE THE COST OF THE PROJECT BY COMPLETING THE PROJECT COSTS CHART ON THE FOLLOWING PAGE. JUSTIFY THE COST OF THE PROJECT.
- ALL PROJECTS SHOULD HAVE A PROJECT COST OF AT LEAST \$3,000 ON LINE F (MINIMUM CON FILING FEE). CON FILING FEE SHOULD BE CALCULATED ON LINE D.
- THE COST OF ANY LEASE (BUILDING, LAND, AND/OR EQUIPMENT) SHOULD BE BASED ON FAIR MARKET VALUE OR THE TOTAL AMOUNT OF THE LEASE PAYMENTS OVER THE INITIAL TERM OF THE LEASE, WHICHEVER IS GREATER. NOTE: THIS APPLIES TO ALL EQUIPMENT LEASES INCLUDING BY PROCEDURE OR "PER CLICK" ARRANGEMENTS. THE METHODOLOGY USED TO DETERMINE THE TOTAL LEASE COST FOR A "PER CLICK" ARRANGEMENT MUST INCLUDE, AT A MINIMUM, THE PROJECTED PROCEDURES, THE "PER CLICK" RATE AND THE TERM OF THE LEASE.
- THE COST FOR FIXED AND MOVEABLE EQUIPMENT INCLUDES, BUT IS NOT NECESSARILY LIMITED TO, MAINTENANCE AGREEMENTS COVERING THE EXPECTED USEFUL LIFE OF THE EQUIPMENT; FEDERAL, STATE, AND LOCAL TAXES AND OTHER GOVERNMENT ASSESSMENTS; AND INSTALLATION CHARGES, EXCLUDING CAPITAL EXPENDITURES FOR PHYSICAL PLANT RENOVATION OR IN-WALL SHIELDING, WHICH SHOULD BE INCLUDED UNDER CONSTRUCTION COSTS OR INCORPORATED IN A FACILITY LEASE.
- FOR PROJECTS THAT INCLUDE NEW CONSTRUCTION, MODIFICATION, AND/OR RENOVATION; DOCUMENTATION MUST BE PROVIDED FROM A CONTRACTOR AND/OR ARCHITECT THAT SUPPORT THE ESTIMATED CONSTRUCTION COSTS.

The architect's letter supporting the construction cost estimate is provided in Attachment C, Economic Feasibility--1.

On the Project Costs Chart, following this response:

Line A.1, A&E fees, were estimated by the project architect.

Line A.2, legal, administrative, and consultant fees, include costs for the CON process and legal services during project planning.

Line A.5, construction cost, was calculated at \$520,000, or \$250 PSF.

Line A.6, contingency, was estimated by the planning team at 5% of construction costs in line A.5.

Line A.7 includes both fixed and moveable equipment costs. The cost and value of the cardiac PET system are documented by the equipment purchase agreement negotiated by WCS and LlifeScan Leasing, LLC.

Line A.9 includes such costs as miscellaneous minor equipment and furnishings, miscellaneous fees and overhead, and moving expenses, as noted on the form.

SUPPLEMENTAL

PROJECT COSTS CHART --WELLMONT CARDIOLOGY SERVICES CARDIAC PET SERVICE 4:20 pm

A.	Construction and equipm	ent acquired by ဥկդርң	PRe29 PM 4 19	
	 Architectural and En Legal, Administrative Acquisition of Site Preparation of Site Construction Cost Contingency Fund Fixed Equipment (No 		cl CON Filing) 6 tion Contract) er \$50,000)	30,000 30,000 0 520,000 26,000 325,000 60,000 60,000 20,000
В.	Acquisition by gift, donat	tion, or lease:		
	 Facility (inclusive of Building only Land only Equipment (Specify) Other (Specify) 	building and land)		0 0 0 0 0
C.	Financing Costs and Fees	:		
	 Interim Financing Underwriting Costs Reserve for One Year Other (Specify) 	's Debt Service	·	0 0 0 0
D.	Estimated Project Cost (A+B+C)			1,071,000
E.	CON Filing Fee	(\$2.25 per \$1,000 li	ne D)	3,000
F.	Total Estimated Project C	ost (D+E)	TOTAL \$	1,074,000
			Actual Capital Cost Section B FMV	1,074,000 0

C(II).2. IDENTIFY THE FUNDING SOURCES FOR THIS PROJECT.

a. PLEASE CHECK THE APPLICABLE ITEM(S) BELOW AND BRIEFLY SUMMARIZE HOW THE PROJECT WILL BE FINANCED. (DOCUMENTATION FOR THE TYPE OF FUNDING MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND IDENTIFIED AS ATTACHMENT C, ECONOMIC FEASIBILITY—2).

A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;

B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;

____C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;

D. Grants--Notification of Intent form for grant application or notice of grant award;

<u>x</u> E. Cash Reserves--Appropriate documentation from Chief Financial Officer; or

F. Other--Identify and document funding from all sources.

The project cost of \$1,073,410 will be entirely funded by Wellmont Health System. Documentation of this is provided in Attachment C, Economic Feasibility--2.

C(II).3. DISCUSS AND DOCUMENT THE REASONABLENESS OF THE PROPOSED PROJECT COSTS. IF APPLICABLE, COMPARE THE COST PER SQUARE FOOT OF CONSTRUCTION TO SIMILAR PROJECTS RECENTLY APPROVED BY THE HSDA.

ODC renovation projects completed in 2008-2012 ranged from \$52-\$196 PSF construction cost, according to data from the HSDA Registry. See Table Three-A below. Although the HSDA Registry did not compile a similar table for 2008-2012 due to the small number of ODC projects (5) completed in 2012, the Registry has supplied construction cost data for those five projects; see Table Three-B below.

Wellmont Cardiology Services' projected renovation cost of \$250 PSF for this very small space is moderately higher than the third quartile range of costs shown in Table Three-A, but is within the range of costs in Table Three-B. It must be recognized that a very small project like this, with large amounts of costly shielding, can be expected to show a relatively high cost per SF compared to larger projects, because larger projects can spread the site mobilization and related fixed costs over a larger square footage.

Table Three	e-A: Outpatient Diagno Years: 2	ostic Center Const 008-2010	ruction Cost PSF
	Renovated	New	Total
	Construction	Construction	Construction
1 st Quartile	\$51.55/sq ft	none	\$51.55/sq ft
Median	\$122.15/sq ft	none	\$122.15/sq ft
3 rd Quartile	\$196.46/sq ft	none	\$196.46/sq ft

Source: HSDA Registry. CON approved applications for years 2008 through 2010

Table Three-B: Outpatient Diagnostic Center Construction Cost PSF Years: 2012					
CON	ODC / Provider	Renovation Area	Construction Cost / sq ft		
CN09808-044	ImagDent of Memphis	1,746 SF	\$51.55/sq ft		
CN1010-046	Murfreesboro Diagnostic Imaging	9,587 SF	\$122.15/sq ft		
CN1010-047	Cleveland Imaging	911 SF	\$269.91/sq ft		
CN1103-008	E. TN Community Open MRI	795 SF	\$160.38/sq ft		
CN1110-039	St. Thomas OP Imaging	7,737 SF	\$159.69/ sq ft		

Source: HSDA Registry. CON approved ODC projects completed in 2012 (all renovation).

C(II).4. COMPLETE HISTORICAL AND PROJECTED DATA CHARTS ON THE FOLLOWING TWO PAGES--DO NOT MODIFY THE CHARTS PROVIDED OR SUBMIT CHART SUBSTITUTIONS. HISTORICAL DATA CHART REPRESENTS REVENUE AND EXPENSE INFORMATION FOR THE LAST THREE (3) YEARS FOR WHICH COMPLETE DATA IS AVAILABLE FOR THE INSTITUTION. PROJECTED DATA CHART REQUESTS INFORMATION FOR THE TWO YEARS FOLLOWING COMPLETION OF THIS PROPOSAL. PROJECTED DATA CHART SHOULD INCLUDE REVENUE AND EXPENSE PROJECTIONS FOR THE PROPOSAL ONLY (I.E., IF THE APPLICATION IS FOR ADDITIONAL BEDS, INCLUDE ANTICIPATED REVENUE FROM THE PROPOSED BEDS ONLY, NOT FROM ALL BEDS IN THE FACILITY).

See the following pages for the Projected Data Chart, with notes where applicable. No Historic Data Chart is required because this service has not been offered in the past by this particular applicant (WCS, Inc.) within the Wellmont system.

76 PROJECTED DATA CHART -- WELLMONT CARDIOLOGY SERVICES CARDIAC PET SERVICE

Give information for the two (2) years following the completion of this proposal. 2013 APR 15 PN 3: 09 The fiscal year begins in January. Year 2014 Year 2015 Α. Utilization Data (Cardiac PET Procedures) 1,500 1,500 В. Revenue from Services to Patients 1.0 Inpatient Services 2. **Outpatient Services** 5,517,435 5,517,435 3. **Emergency Services** 4. Other Operating Revenue (Specify) **Gross Operating Revenue** 5,517,435 5,517,435 Deductions for Operating Revenue C. 1. Contractual Adjustments 3,338,048 3,338,048 2. Provision for Charity Care 193,110 193,110 3. Provisions for Bad Debt 275,872 275,872 **Total Deductions** 3,807,030 3,807,030 **NET OPERATING REVENUE** 1,710,405 1,710,405 \$ D. Operating Expenses 1. Salaries and Wages 142,000 146,260 2. Physicians Salaries and Wages 372,000 372,000 3. Supplies 588,000 605,640 4. Taxes 5. Depreciation 92,000 92,000 6. Rent 75,000 75,000 7. Interest, other than Capital 8. Management Fees a. Fees to Affiliates 51,312 51,312 b. Fees to Non-Affiliates 80,000 80,000 9. Other Expenses (Specify) See notes 67,500 67,500 **Total Operating Expenses** 1,467,812 1,489,712 E. Other Revenue (Expenses) -- Net (Specify) \$ \$ NET OPERATING INCOME (LOSS) 242,593 220,693 F. Capital Expenditures 1. Retirement of Principal \$ 2. Interest **Total Capital Expenditures** 0 0 NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES 242,593 220,693

NOTES TO PROJECTED DATA CHART

D.1, Physician Salaries and Wages--\$372,000

This line item is composed of two expenses. First, as required by the accreditation agency, there will be a compensated Medical Director to provide oversight of the operation. Second, the amount includes estimated payments to the several WCS cardiologists (Board certified in Nuclear Cardiology) who will interpret the cardiac PET studies. The applicant will bill a global fee, from which the physicians will be paid for their professional interpretation.

D.8, Fees to Affiliates & Non-Affiliates--\$51,312 & \$80,000 respectively

Affiliates: Billing services by another Wellmont Health System organization will be compensated at 3% of net operating revenue (\$1,710,405).

Non-affiliates: This is for a service/maintenance agreement.

D.9, Other Expenses--\$67,500

This line item includes \$30,000 for utilities @\$20 per scan. It also includes a lump sum estimate by management, of \$25 per scan to cover administrative, coding, transcription and related costs incurred by the practice, for provision of this service.

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Nine: Average Charges, Dedu WCS Cardiac PET		arges
	CY2014	CY2015
Procedures	1,500	1,500
Average Gross Charge Per Procedure	\$3,678	\$3,678
Average Deduction Per Procedure	\$2,538	\$2,538
Average Net Charge (Net Operating Revenue) Per Procedure	\$1,140	\$1,140
Average Net Operating Income Per Procedure After Capital Expenditures	\$162	\$162

C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

The applicant intends to keep the service's average net revenue level close to current charges at Molecular Imaging Alliance in Gray. The WCS service will have a moderate positive operating margin from its outset, and will not generate financial losses that would need to be shifted to other services and patients. The applicant will operate the scanner under its group provider number (unless required to operate it as an ODC) so that it will not have an initial cash flow issue while waiting for a new Medicare provider number. In the event it is required to open as an ODC with a new provider number, WCS and Wellmont Health System have the financial resources to carry the service until it has positive cash flow.

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

The projected average gross charge for this WCS service is higher than that of the ODC in Gray in CY2012; but WCS's projected average net operating revenue (receipts), or its impact on payors, will not be higher.

Table Ten: Comparative Gross Cl	harges Per Cardiac PET Scan
Provider	Average Gross / Net Revenue
Molecular Imaging Alliance ODC, Gray	2012: \$1,764 / \$1,764
WCS at The Heart Center, Kingsport	Proposed, CY2014: \$3,678 / \$1,140
Molecular Imaging Alliance, Johnson City	Proposed, CY2014: \$3,133 / \$1,710

Source: ODC records; applicant's Projected Data Chart, this application.

The following page contains Table Eleven, a chart showing the most frequent procedures to be performed, with their current Medicare reimbursement, and their projected Years One and Two utilization and average gross charges.

April 26, 2013 1:15 pm

	Table Eleven:		Sardiology	Services C	Wellmont Cardiology Services Cardiac PET Service	rvice		
		Charge Data for Most Frequent Procedures	or Most Fr	equent Pro	cedures			
	Ř		Av	Average Gross Charge	Charge		Utilization	
TOT		Current						
DRG	Descriptor	Allowable	Current	Year 1	Year 2	Current	Year 1	Year 2
78492	78492 Myocardial imaging, positron							1
	emission tomography (PET),							
	perfusion; multiple studies at rest							
	and/or stress	1,099.43	3,298.29	3,133.38	2,976.71	254	1,500	1,500
78459	78459 PET MYOCARDIAL IMAGING	\$1,082	3,244.80	3,082.56	2,928.43	0	0	0
78491	78491 PET MYOCARDIAL IMAGING SINGL	\$1,083	3,248.46	3,086.04	2,931.74	0	0	0
A9526	A9526 Nitrogen N-13 Ammonia	*Invoice Total	320.00	320.00	320.00	254	1,500	1,500
J2785	J2785 Lexiscan	53.64	160.91	482.72	1,448.17	254	1,500	1,500
Source:	Practice Management							

Practice Management *Per CAHABA - Invoice Total Required. \$160 each dose, 2 doses per patient = \$320 (Current volume conducted using a mobile PET at HVMC in CY2012)

C(II).7. DISCUSS HOW PROJECTED UTILIZATION RATES WILL BE SUFFICIENT TO MAINTAIN COST-EFFECTIVENESS.

The current internal need for 1,500 scans per year will assure this project of operating with a positive cash flow. See the Projected Data Chart.

C(II).8. DISCUSS HOW FINANCIAL VIABILITY WILL BE ENSURED WITHIN TWO YEARS; AND DEMONSTRATE THE AVAILABILITY OF SUFFICIENT CASH FLOW UNTIL FINANCIAL VIABILITY IS MAINTAINED.

The applicant will operate the service under its group provider number, so it will not have an initial cash flow issue while waiting for a new Medicare provider number. In the event it is required to open as an ODC with a new provider number, WCS and Wellmont Health System have the financial resources to carry the service until it has positive cash flow.

C(II).9. DISCUSS THE PROJECT'S PARTICIPATION IN STATE AND FEDERAL REVENUE PROGRAMS, INCLUDING A DESCRIPTION OF THE EXTENT TO WHICH MEDICARE, TENNCARE/MEDICAID, AND MEDICALLY INDIGENT PATIENTS WILL BE SERVED BY THE PROJECT. IN ADDITION, REPORT THE ESTIMATED DOLLAR AMOUNT OF REVENUE AND PERCENTAGE OF TOTAL PROJECT REVENUE ANTICIPATED FROM EACH OF TENNCARE, MEDICARE, OR OTHER STATE AND FEDERAL SOURCES FOR THE PROPOSAL'S FIRST YEAR OF OPERATION.

WCS participates in Medicare and in all area TennCare contracts and Virginia Medicaid. Its projected payor mix for this proposed new nuclear medicine service is 68.8% Medicare, and 3.4% TennCare. This reflects CY2012 experience with nuclear medicine imaging services at WCS. Indigent care has also been projected at 3.5% of gross charges in CY2014.

Table Twelve: Medicar	e and TennCare/Medic	aid Revenues, Year One
	Medicare TennCare/M	
Gross Revenue	\$3,795,995	\$187,593
Percent of Gross Revenue	68.8%	3.4%

PROVIDE COPIES OF THE BALANCE SHEET AND INCOME C(II).10. STATEMENT FROM THE MOST RECENT REPORTING PERIOD OF THE AUDITED FINANCIAL RECENT INSTITUTION, AND THE MOST STATEMENTS WITH ACCOMPANYING NOTES, IF APPLICABLE. NEW PROJECTS, PROVIDE FINANCIAL INFORMATION FOR THE CORPORATION, PARTNERSHIP, OR PRINCIPAL PARTIES INVOLVED WITH THE PROJECT. COPIES MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND LABELED AS ATTACHMENT C, ECONOMIC FEASIBILITY--10.

These are provided as Attachment C, Economic Feasibility--10.

C(II)11. DESCRIBE ALL ALTERNATIVES TO THIS PROJECT WHICH WERE CONSIDERED AND DISCUSS THE ADVANTAGES AND DISADVANTAGES OF EACH ALTERNATIVE, INCLUDING BUT NOT LIMITED TO:

- A. A DISCUSSSION REGARDING THE AVAILABILITY OF LESS COSTLY, MORE EFFECTIVE, AND/OR MORE EFFICIENT ALTERNATIVE METHODS OF PROVIDING THE BENEFITS INTENDED BY THE PROPOSAL. IF DEVELOPMENT OF SUCH ALTERNATIVES IS NOT PRACTICABLE, THE APPLICANT SHOULD JUSTIFY WHY NOT, INCLUDING REASONS AS TO WHY THEY WERE REJECTED.
- B. THE APPLICANT SHOULD DOCUMENT THAT CONSIDERATION HAS BEEN GIVEN TO ALTERNATIVES TO NEW CONSTRUCTION, E.G., MODERNIZATION OR SHARING ARRANGEMENTS. IT SHOULD BE DOCUMENTED THAT SUPERIOR ALTERNATIVES HAVE BEEN IMPLEMENTED TO THE MAXIMUM EXTENT PRACTICABLE.

If WCS does not acquire this equipment and relocate it to Kingsport where it can be medically supervised and highly utilized, it may lose what limited access it now has to cardiac PET imaging. The ODC in Gray is the region's only source of service. It intends to move to Johnson City, doubling the distance between Kingsport and the service. The ODC has also told its equipment leasing company that it will lease only one PET unit at the new location; and there is the possibility that it will be so busy in another few years that WCS patients will have even less access to it than today, even if they are willing to drive the extra distance into Johnson City.

It is economical to be able to acquire well-maintained cardiac PET equipment whose performance is familiar to the applicant. Alternatives on the market might not prove to be as reliable or satisfactory.

The applicant is utilizing existing office space for the project, rather than seeking expensive new construction.

C(III).1. LIST ALL EXISTING HEALTH CARE PROVIDERS (I.E., HOSPITALS, NURSING HOMES, HOME CARE ORGANIZATIONS, ETC.) MANAGED CARE ORGANIZATIONS, ALLIANCES, AND/OR NETWORKS WITH WHICH THE APPLICANT CURRENTLY HAS OR PLANS TO HAVE CONTRACTUAL AND/OR WORKING RELATIONSHIPS, E.G., TRANSFER AGREEMENTS, CONTRACTUAL AGREEMENTS FOR HEALTH SERVICES.

WCS is under the organizational umbrella of the Wellmont Health System in Kingsport, with one of the State's largest tertiary hospitals only minutes away. The WCS building in Kingsport, called The Heart Center, is jointly occupied by WCS staff and staff of Holston Valley Medical Center. There is no shortage of working relationships between the applicant and any level of healthcare provider that might be needed. No emergency transfer agreement will be needed because the service will be within a medical practice with numerous physicians and nurses available as first responders to any emergency needs of the patient being scanned.

C(III).2. DESCRIBE THE POSITIVE AND/OR NEGATIVE EFFECTS OF THE PROPOSAL ON THE HEALTH CARE SYSTEM. PLEASE BE SURE TO DISCUSS ANY INSTANCES OF DUPLICATION OR COMPETITION ARISING FROM YOUR PROPOSAL, INCLUDING A DESCRIPTION OF THE EFFECT THE PROPOSAL WILL HAVE ON THE UTILIZATION RATES OF EXISTING PROVIDERS IN THE SERVICE AREA OF THE PROJECT.

This is not a duplicative or even a competitive project. It is only a change in location and ownership of a CON-approved cardiac PET system that has been serving the same area counties that WCS serves. The cardiac PET system's utilization will greatly increase as a result of moving north from Gray. However, all of its increased utilization will come from WCS's own internal procedure conversions and follow-up tests, not from volumes of cardiac PET performed by any other provider.

The only current or approved provider of this service in the region, Molecular Imaging Alliance, has worked closely with WCS in planning this relocation of services from Gray to the larger medical communities in Johnson City and Kingsport. Molecular does not anticipate that WCS's relocation of one of the Molecular units to Kingsport will have any detrimental impact on its cardiac PET utilization in Johnson City. Both Molecular and WCS see this as an orderly development of services that will improve patient care and will lead to much higher utilization of this specialized diagnostic service at both locations.

C(III).3. PROVIDE THE CURRENT AND/OR ANTICIPATED STAFFING PATTERN FOR ALL EMPLOYEES PROVIDING PATIENT CARE FOR THE PROJECT. THIS CAN BE REPORTED USING FTE'S FOR THESE POSITIONS. IN ADDITION, PLEASE COMPARE THE CLINICAL STAFF SALARIES IN THE PROPOSAL TO PREVAILING WAGE PATTERNS IN THE SERVICE AREA AS PUBLISHED BY THE TENNESSEE DEPARTMENT OF LABOR & WORKFORCE DEVELOPMENT AND/OR OTHER DOCUMENTED SOURCES.

Please see the following page for a chart of projected FTE's and salary ranges.

The Department of Labor and Workforce Development website indicates the following Upper East Tennessee region's annual salary information for clinical employees of this project:

Table Thirte	en: TDOL Surve	yed Average Sala	ries for Upper Ea	st Tennessee
Position	Entry Level	Mean	Median	Experienced
RN	\$38,280	\$53,160	\$48,840	\$60,600
Nuclear				
Medicine Tech	\$54,290	\$60,050	\$59,210	\$62,940

Table Fourteen- Wellmont Cardiology Services Cardiac PET Service	Ilmont Car	diology Ser	vices Car	diac PET Service
	Staffing	Staffing Requirements	ents	
	Current	Year One Year Two	Year Two	
Position Type (RN, etc.)	FTE's	FTE's		Salary Range (Hourly or Annual)
Registered Nurse	0	1	~	\$22 - \$32 / Hour
Nuclear Medicine Technologist	0	1	_	\$24 - \$30 / Hour
Clerical (Reception/Front Office)	0	₹		\$9 - \$13 / HOUR
Total FTE's	0	8	က	

Source: WCS Management

C(III).4. DISCUSS THE AVAILABILITY OF AND ACCESSIBILITY TO HUMAN RESOURCES REQUIRED BY THE PROPOSAL, INCLUDING ADEQUATE PROFESSIONAL STAFF, AS PER THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, AND/OR THE DIVISION OF MENTAL RETARDATION SERVICES LICENSING REQUIREMENTS.

The project requires only three additional clinical staff. The applicant manages a very large employee base and has been successful in the past in filling its positions.

C(III).5. VERIFY THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSING CERTIFICATION AS REQUIRED BY THE STATE OF TENNESSEE FOR MEDICAL/CLINICAL STAFF. THESE INCLUDE, WITHOUT LIMITATION, REGULATIONS CONCERNING PHYSICIAN SUPERVISION, CREDENTIALING, ADMISSIONS PRIVILEGES, QUALITY ASSURANCE POLICIES AND PROGRAMS, UTILIZATION REVIEW PPOLICIES AND PROGRAMS, RECORD KEEPING, AND STAFF EDUCATION.

The applicant so verifies. The applicant is familiar with ODC licensing requirements.

C(III).6. DISCUSS YOUR HEALTH CARE INSTITUTION'S PARTICIPATION IN THE TRAINING OF STUDENTS IN THE AREAS OF MEDICINE, NURSING, SOCIAL WORK, ETC. (I.E., INTERNSHIPS, RESIDENCIES, ETC.).

Wellmont Health System and Wellmont Cardiology Services support a wide variety of medical related training and educational programs. WCS physicians support the Family Medicine and Internal Medicine training program operated by East Tennessee State University. WCS also supports the rural-based, Family Medicine residency program operated by Wellmont Health System in formal collaboration with the Debusk College of Osteopathic Medicine. WCS has numerous training and educational affiliations with academic institutions throughout the southeastern U.S., which supports nursing training, imaging technologists training and the training of other allied health professionals. WCS operates a division called "Cardiovascular University" which offers hands-on training programs in Kingsport to cardiologists, vascular surgeons, nurse practitioners, physician assistants and other healthcare professionals.

PLEASE VERIFY, AS APPLICABLE, THAT THE APPLICANT C(III).7(a). HAS REVIEWED AND UNDERSTANDS THE LICENSURE REQUIREMENTS OF THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, THE DIVISION OF APPLICABLE **MENTAL** RETARDATION SERVICES, AND/OR ANY MEDICARE REQUIREMENTS.

The applicant so verifies.

C(III).7(b). PROVIDE THE NAME OF THE ENTITY FROM WHICH THE RECEIVE LICENSURE, APPLICANT HAS RECEIVED OR WILL CERTIFICATION, AND/OR ACCREDITATION

LICENSURE:

Outpatient Diagnostic Facility (proposed, if required),

fromTennessee Department of Health

Radioactive Materials License

from Tennessee Department of Environment

and Conservation

CERTIFICATION:

Medicare Certification from CMS

TennCare Certification from TDH

ACCREDITATION: Will seek Intersocietal Accreditation Commission (ICA)

accreditation in Nuclear Cardiology, Nuclear Medicine, and Positron Emission Tomography.

IF AN EXISTING INSTITUTION, PLEASE DESCRIBE THE C(III).7(c). LICENSING, CERTIFYING, CURRENT **STANDING** WITH ANY ACCREDITING AGENCY OR AGENCY.

The applicant's physicians are all licensed to practice medicine, by the State Board of Medical Examiners. The WCS group practice is certified for participation in Medicare and Medicaid/TennCare.

C(III).7(d). FOR EXISTING LICENSED PROVIDERS, DOCUMENT THAT ALL DEFICIENCIES (IF ANY) CITED IN THE LAST LICENSURE CERTIFICATION AND INSPECTION HAVE BEEN ADDRESSED THROUGH AN APPROVED PLAN OF CORRECTION. PLEASE INCLUDE A COPY OF THE MOST RECENT LICENSURE/CERTIFICATION INSPECTION WITH AN APPROVED PLAN OF CORRECTION.

Not applicable to a new service.

C(III)8. DOCUMENT AND EXPLAIN ANY FINAL ORDERS OR JUDGMENTS ENTERED IN ANY STATE OR COUNTRY BY A LICENSING AGENCY OR COURT AGAINST PROFESSIONAL LICENSES HELD BY THE APPLICANT OR ANY ENTITIES OR PERSONS WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE APPLICANT. SUCH INFORMATION IS TO BE PROVIDED FOR LICENSES REGARDLESS OF WHETHER SUCH LICENSE IS CURRENTLY HELD.

None.

C(III)9. IDENTIFY AND EXPLAIN ANY FINAL CIVIL OR CRIMINAL JUDGMENTS FOR FRAUD OR THEFT AGAINST ANY PERSON OR ENTITY WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE PROJECT.

None.

C(III)10. IF THE PROPOSAL IS APPROVED, PLEASE DISCUSS WHETHER THE APPLICANT WILL PROVIDE THE THSDA AND/OR THE REVIEWING AGENCY INFORMATION CONCERNING THE NUMBER OF PATIENTS TREATED, THE NUMBER AND TYPE OF PROCEDURES PERFORMED, AND OTHER DATA AS REQUIRED.

Yes. The applicant will provide the requested data consistent with Federal HIPAA requirements.

PROOF OF PUBLICATION

Attached.

DEVELOPMENT SCHEDULE

1. PLEASE COMPLETE THE PROJECT COMPLETION FORECAST CHART ON THE NEXT PAGE. IF THE PROJECT WILL BE COMPLETED IN MULTIPLE PHASES, PLEASE IDENTIFY THE ANTICIPATED COMPLETION DATE FOR EACH PHASE.

The Project Completion Forecast Chart is provided after this page.

2. IF THE RESPONSE TO THE PRECEDING QUESTION INDICATES THAT THE APPLICANT DOES NOT ANTICIPATE COMPLETING THE PROJECT WITHIN THE PERIOD OF VALIDITY AS DEFINED IN THE PRECEDING PARAGRAPH, PLEASE STATE BELOW ANY REQUEST FOR AN EXTENDED SCHEDULE AND DOCUMENT THE "GOOD CAUSE" FOR SUCH AN EXTENSION.

Not applicable. The applicant anticipates completing the project within the period of validity.

PROJECT COMPLETION FORECAST CHARTER 15 PM 3: 09

Enter the Agency projected Initial Decision Date, as published in Rule 68-11-1609(c):

July 24, 2013

Assuming the CON decision becomes the final Agency action on that date, indicate the number of days from the above agency decision date to each phase of the completion forecast.

PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Architectural & engineering contract signed	6	8/13
2. Construction documents approved by TDH	66	10/13
3. Construction contract signed	72	10/13
Building permit secured	74	10/13
5. Site preparation completed	na	na
6. Building construction commenced	81	10/13
7. Construction 40% complete	105	10/13
8. Construction 80% complete	121	11/13
9. Construction 100% complete	126	12/13
10. * Issuance of license (if required)	136	12/13
11. *Initiation of service	166	1/14
12. Final architectural certification of payment	256	4/14
13. Final Project Report Form (HF0055)	316	6/14

^{*} For projects that do NOT involve construction or renovation: please complete items 10-11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

INDEX OF ATTACHMENTS

Ownership--Legal Entity and Organization Papers A.4

A.6 Site Control

B.II.E.1. Fixed Major Medical Equipment--FDA Approval Documentation

B.II.E.3 Major Medical Equipment--Vendor Quotations / Draft Leases

B.III. Plot Plan

Floor Plan

C, Need--3

C, Economic Feasibility--1 Documentation of Construction Cost Estimate

Letters of Intent

Service Area Maps

C, Economic Feasibility--2 Documentation of Availability of Funding

C, Economic Feasibility--10 **Financial Statements**

Miscellaneous Information

Support Letters

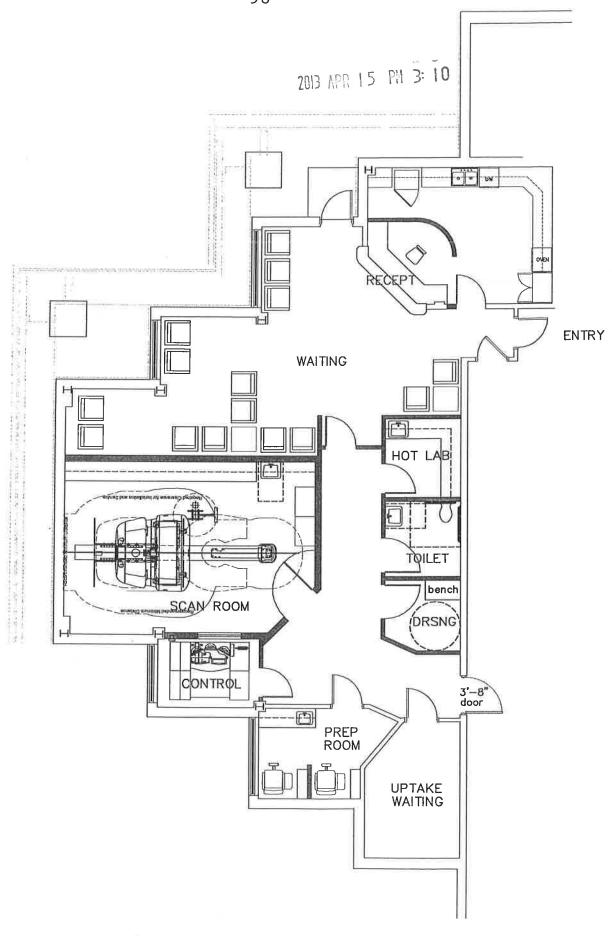
B.IV.

C, Need--1.A.3.

B.III.--Plot Plan

C4.1

B.IV.--Floor Plan



C, Need--1.A.3.e. Letters of Intent



Precision Nuclear, LLC

April 15, 2013

Rob Gregory Lifescan, TN 830 Suncrest Drive, Suite 2 Gray, TN 37615

Dear Mr. Gregory:

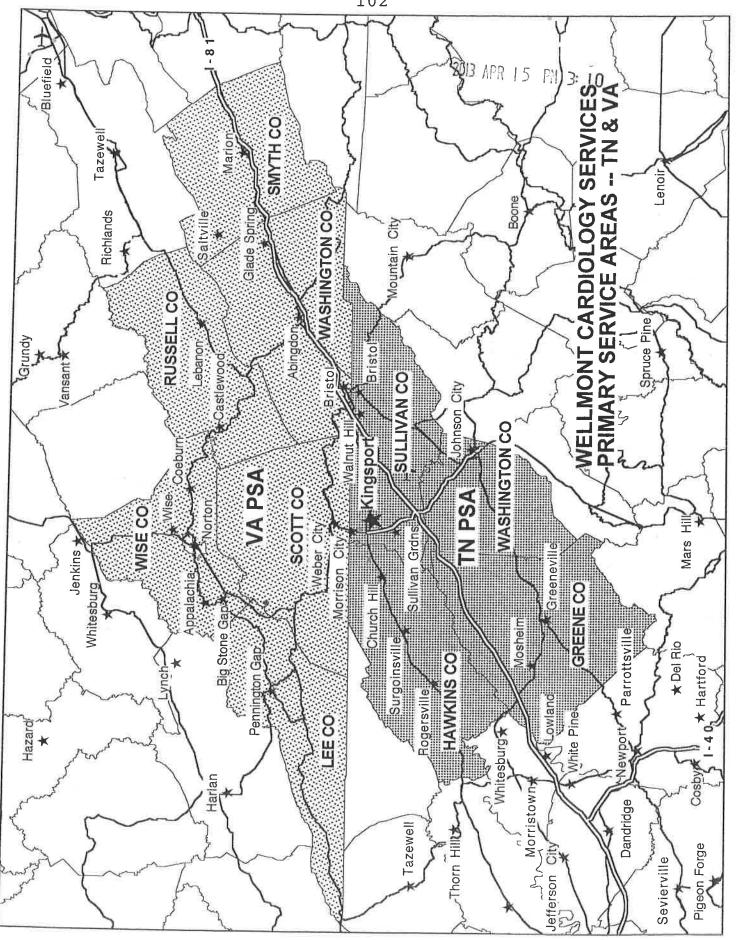
This letter is to confirm the ability and willingness of Precision Nuclear, LLC to supply your PET imaging system and the PET imaging system at CVA Heart Institute with unit dose [N13]NH₃ Ammonia for cardiac PET perfusion imaging for the calendar years of 2013 and 2014 at their proposed locations in Johnson City and Kingsport, Tennessee, should their relocation from the existing location in Gray, Tennessee, be approved by the State of Tennessee. If you have any questions or concerns, please do not hesitate to contact me directly.

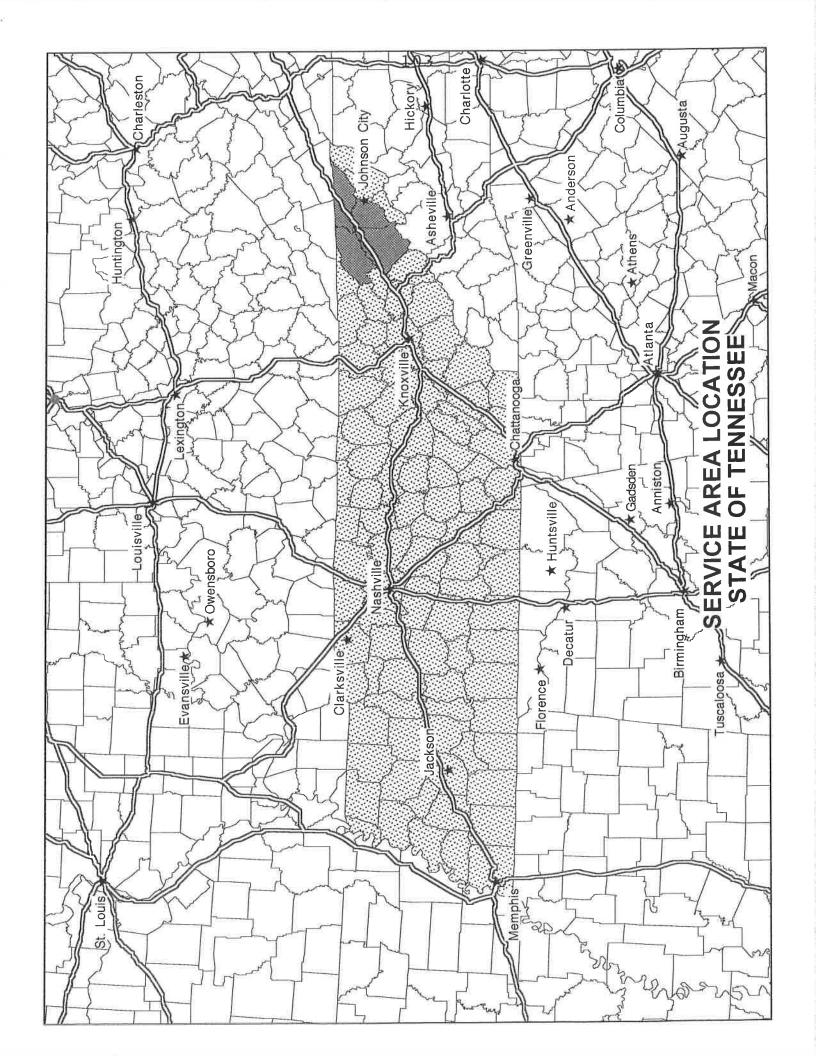
Sincerely,

Alan W. Arp, Pharm.D.

President, Precision Nuclear, LLC

C, Need--3 Service Area Maps





C, Economic Feasibility--1 Documentation of Construction Cost Estimate



April 12, 2013

Mr. Jim Moore, Vice President of Facilities Wellmont Health System CVA Heart Institute in Kingsport 2050 Meadowview Parkway Kingsport, Tennessee 37660

Subject:

Verification for Construction Cost Estimate

New Outpatient Diagnostic Center - Cardiac PET Lab

Kingsport, Tennessee

CalnRashWest, Architects, an architectural firm in Kingsport, Tennessee, has reviewed the cost data for the above referenced project, for which this firm has provided a preliminary design. The stated renovated construction budget cost is approximately \$520,000.00. [In providing opinions of probable construction cost, the Client understands that the Architect has no control over the cost or availability of labor, equipment or materials, or over market conditions of the final selected Contractor's method of pricing, and that the Architect's opinions of probable construction costs are made on the basis of the Architect's professional judgment and experience. The Architect makes no warranty, express or implied, that the bids or negotiated cost of the Work will not vary from the Architect's opinion of probable construction cost.]

It is our opinion that at this time, the projected renovation construction budget cost is reasonable for this type and size of project and compares appropriately with similar projects in this market.

The current building codes applicable to the project, as the date of the letter, will be:

International Building Code, 2006 NFPA 101 Life Safety Code, 2006 FGI Guidelines for Design and Construction of Health Care Facilities, 2010 Edition ANSIA-117.1, 2003

Sincerely,

M. Hiram Rash, AIA TN License # 15351

CainRashWest, Architects

C, Economic Feasibility--2
Documentation of Availability of Funding



April 15, 2013

Melanie M. Hill, Executive Director Tennessee Health Services and Development Agency Andrew Jackson State Office Building, Suite 850 500 Deaderick Street Nashville, Tennessee 37243

RE: CON Application for Cardiac PET Service and ODC Licensure

Wellmont Cardiology Services, Inc., Kingsport, Sullivan County

Dear Mrs. Hill:

Wellmont Cardiology Services, Inc., whose only member/owner is Wellmont Health System, is applying for a Certificate of Need to add the subject service to the Wellmont CVA Heart Institute campus in Kingsport, and if required, to license the service as an Outpatient Diagnostic Center.

As Senior Vice President, Finance of Wellmont Health System, I am writing to confirm that we will provide in cash the approximately \$1,074,000 in capital costs required to implement this project. The organization's financial statements are provided in the application.

Sincerely,

Todd J. Dougan, CPA

Sr. Vice President, Finance

Wellmont Health System 1905 American Way

Kingsport, TN 37660

423-230-8512

423-230-8511 (fax)

Todd.Dougan@Wellmont.org

C, Economic Feasibility--10 Financial Statements

1:15 pm



WELLMONT HEALTH SYSTEM AND AFFILIATES

Consolidated Financial Statements

June 30, 2012 and 2011

(With Independent Auditors' Report Thereon)



KPMG LLP Suite 1000 401 Commerce Street Nashville, TN 37219-2422

Independent Auditors' Report

The Board of Directors Wellmont Health System:

We have audited the accompanying consolidated balance sheets of Wellmont Health System and affiliates (Wellmont) as of June 30, 2012 and 2011, and the related consolidated statements of operations and changes in net assets, and cash flows for the years then ended. These consolidated financial statements are the responsibility of Wellmont's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of Wellmont's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Wellmont Health System and affiliates as of June 30, 2012 and 2011, and the consolidated results of their operations and changes in their net assets, and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

As discussed in note 2 to the consolidated financial statements, Wellmont changed its presentation of provision for bad debts as a result of the adoption of Accounting Standards Update No. 2011-07, Health Care Entities: Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debts, and the Allowance for Doubtful Accounts for Certain Health Care Entities.

KPMG LLP

October 24, 2012

WELLMONT HEALTH SYSTEM AND AFFILIATES

Consolidated Balance Sheets

June 30, 2012 and 2011

(Dollars in thousands)

Assets	-	2012	2011
Current assets: Cash and cash equivalents Assets limited as to use, required for current liabilities Patient accounts receivable, less allowance for uncollectible accounts of	\$	44,930 4,372	36,558 1,902
approximately \$25,656 and \$24,246 in 2012 and 2011, respectively Other receivables Inventories Prepaid expenses and other current assets		108,265 23,805 17,862 7,462	101,565 9,904 17,830 7,163
Total current assets	-	206,696	174,922
Assets limited as to use, net of current portion Land, buildings, and equipment, net		339,030 458,048	319,387 454,937
Other assets: Long-term investments Investments in affiliates Deferred debt expense, net Goodwill Other		36,633 32,646 5,419 17,090 651	36,437 31,177 5,847 16,721 1,875
	_	92,439	92,057
Total assets	\$ =	1,096,213	1,041,303
Liabilities and Net Assets			
Current liabilities: Current portion of long-term debt Accounts payable and accrued expenses Estimated third-party payor settlements Current portion of other long-term liabilities	\$	11,913 81,243 15,535 5,782	9,273 70,943 9,533 8,527
Total current liabilities		114,473	98,276
Long-term debt, less current portion Other long-term liabilities, less current portion		459,654 54,060	458,882 42,384
Total liabilities	_	628,187	599,542
Net assets: Unrestricted Temporarily restricted Permanently restricted		458,218 5,739 1,304	434,661 3,570 1,174
Total net assets attributable to Wellmont		465,261	439,405
Noncontrolling interests	_	2,765	2,356_
Total net assets		468,026	441,761
Commitments and contingencies	_		
Total liabilities and net assets	\$ =	1,096,213	1,041,303

See accompanying notes to consolidated financial statements.

SUPPLEMENTAL-#1 April 26, 2013 1:15 pm

WELLMONT HEALTH SYSTEM AND AFFILIATES

Consolidated Statements of Operations and Changes in Net Assets

2013 AFR 26 PM 1: 21

Years ended June 30, 2012 and 2011 (Dollars in thousands)

	2012	2011
Revenue:		
	\$ 813,229	767,450
Provision for bad debt	(71,407)	(37,858)
Net patient revenue less provision for bad debt	741,822	729,592
Other revenues	47,904	29,799
Total revenue	789,726	759,391
Expenses:		
Salaries and benefits	368,772	347,185
Medical supplies and drugs	164,397	160,565
Purchased services	79,509	80,348
Interest	21,677	20,750
Depreciation and amortization	46,403	46,059
Other	86,645	87,319
Total expenses	767,403	742,226
Income from operations	22,323	17,165
Nonoperating gains (losses):		
Investment income	17,272	10,383
Derivative valuation adjustments	1,807	1,355
Other, net		(519)
Gain on refinancing	-	1,042
Nonoperating gains, net	19,079	12,261
Revenue and gains in excess of expenses and losses before discontinued operations	41,402	29,426
Discontinued operations	88	44
Revenue and gains in excess of expenses and losses	41,490	29,470
Income attributable to noncontrolling interests	(1,670)	(1,238)
Revenues and gains in excess of expenses and losses attributable to Wellmont	39,820	28,232
Other changes in unrestricted net assets:		
Change in net unrealized gains on investments	(9,534)	42,186
Net assets released from restrictions for additions to land, buildings, and equipment	3,766	2,852
Change in the funded status of benefit plans and other	(10,495)	2,771
Increase in unrestricted net assets	23,557	76,041
Changes in temporarily restricted net assets:		
Contributions	6,661	2,566
Net assets released from temporary restrictions	(4,492)	(3,547)
Increase (decrease) in temporarily restricted net assets	2,169	(981)
Changes in permanently restricted net assets – investment income	130	6
Changes in noncontrolling interests:		
Income attributable to noncontrolling interests	1,670	1,238
Distributions to noncontrolling interests	(1,261)	(1,178)
Change in noncontrolling percentages	(1,201)	(92)
Increase (decrease) in noncontrolling interests	409	(32)
Change in net assets	26,265	75,034
Net assets, beginning of year	441,761	366,727
N. d. C. C.	468.026	441,761
·	400,020	771,701

See accompanying notes to consolidated financial statements.

Miscellaneous Information

Recent advances in cardiac PET and PET/CT M 3: 10 myocardial perfusion imaging

Gary V. Heller, MD, PhD, a Dennis Calnon, MD, and Sharmila Dorbala, MDc

Cardiovascular imaging has gained an important role in the evaluation of patients with either known or suspected coronary artery disease. The choices have expanded, imaging procedures have improved. Currently, testing procedures include echocardiography, magnetic resonance imaging, cardiac CTA, cardiac catheterization, and nuclear myocardial perfusion imaging with either single photon emission computed tomography (SPECT) or positron emission tomography (PET). Each of these imaging modalities has its strengths and weaknesses. However, SPECT myocardial perfusion imaging has emerged as a reliable and widely available tool for physicians to use in the assessment of their patient for the exclusion or presence and severity of CAD. Recently, cardiac PET has emerged as an alternative to SPECT imaging.

Cardiac positron emission tomography (PET) imaging has gained considerable support and use in the field of cardiovascular imaging over the past several years. For example, delivery of the most accessible PET tracer, Rubidium-82 (RB-82) has quadrupled; the use of myocardial viability studies has increased, and the value of cardiac PET perfusion imaging is now being recognized. This recent increase in activity and interest has been spearheaded by several factors, such as availability of the camera technology, advances in cardiac PET acquisition and perfusion procedures, improved display procedures and software, as well as literature supporting the diagnostic and prognostic accuracy of PET perfusion

imaging. This review will highlight cardiac PET as presented in a recent symposium with regards to differences between SPECT imaging and PET, literature supporting cardiac PET for both diagnostic accuracy and risk stratification, and features of cardiac PET/CT that differentiate it from SPECT. The review includes recent literature advances.

SINGLE-PHOTON-COMPUTED TOMOGRAPHIC IMAGING: STRENGTHS AND WEAKNESSES

Single-photon-computed tomographic imaging (SPECT) has been successfully performed for over 30 years. Over 6 million studies are performed annually with a rich literature confirming both diagnostic and accuracy prognostic value. Over these years, considerable advancement has been made in the technology to improve image quality and shorten acquisition protocols. Its strengths are many including standardized protocols, ease of use, availability, and established guidelines (Table 1).

Despite these advances, however, several limitations of SPECT remain (Table 2). It is well recognized that SPECT techniques frequently underestimate the degree of ischemia and therefore the presence of multivessel coronary artery disease. The stress imaging protocols are inefficient and require much longer time than similar protocols for echo, CT, or even cardiac catheterization (2.5-4 vs 1 hour or less for other procedures). Recent advancements have targeted these long procedures including shortened acquisition times, as recently summarized by Slomka et al. Attenuation artifact with SPECT imaging is commonplace despite efforts to identify using techniques such as prone imaging, attenuation correction, and/or ECG-gated SPECT imaging. Tracer activity in the liver and gut structures are common with SPECT imaging, particularly popular technetium-based imaging agents. As a result, interpretative confidence is sometimes lacking.

Hartford Hospital, Hartford, CT; Nuclear Cardiology Laboratory, McConnell Heart Hospital at Riverside Methodist Hospital, Columbus, OH; Nuclear Medicine Laboratory, Brigham and Women s Hospital, Boston, MA.

The review includes a summary of presentations made by the authors

From the Nuclear Cardiology Laboratory, Henry Low Heart Center, a

The review includes a summary of presentations made by the authors at a symposium sponsored by the same organization at the Annual Scientific Sessions of ASNC in San Diego, September 10-14, 2007 as well as recent advancements in the literature.

Received for publication Jun 18, 2009; final revision accepted Aug 16, 2009.

Reprint requests: Gary V. Heller, MD, PhD, Nuclear Cardiology Laboratory, Henry Low Heart Center, Hartford Hospital, 80 Seymour Street, P.O. Box 5037, Hartford, CT 06102-5037, USA; gheller@harthosp.org.

J Nucl Cardiol 2009;16:962-9.

1071-3581/\$34.00

Copyright © 2009 by the American Society of Nuclear Cardiology. doi:10.1007/s12350-009-9142-5

CARDIAC PET PERFUSION IMAGING AS AN ALTERNATIVE TO SPECT

An alternative to SPECT imaging is cardiac PET perfusion imaging. PET offers many advantages (Table 3). These advantages include higher spatial and contrast resolution, resulting in higher image quality and

Table 1. Strengths of SPECT myocardial perfusion imaging

Standardized protocols

Small, relatively inexpensive camera systems suitable for offices

Well documented literature for diagnostic accuracy Well documented literature for risk stratification ACC/ASNC guidelines, appropriateness criteria Great acceptance by cardiology community

Table 2. Limitations of SPECT myocardial perfusion imaging

SPECT techniques underestimate ischemia severity Imaging protocols are inefficient (commonly 2-4 hours)

Attenuation artifacts are common GI tracer interference is common Interpretation confidence is often lacking

Table 3. Advantages of cardiac PET and PET/CT

Improved image quality
Higher spatial and contrast resolution
Accurate attenuation correction
Higher diagnostic accuracy
Excellent risk stratification
Rapid procedure
Rest and peak stress gating
Added information: blood flow, calcium, coronary CT

improved diagnostic accuracy. Attenuation correction, a technique validated with SPECT but infrequently used, is performed on every PET perfusion study. Excellent data are emerging with regards to risk stratification with PET perfusion. With Rb-82 as the radiotracer, the procedure is rapid (30-40 minutes, in comparison to 2.5-4 hours). Finally, added information such as regional blood flow, calcium scoring, and coronary CT can be provided, depending on instrumentation.

ADVANTAGES OF PET PERFUSION IMAGING

Improved Image Quality

The higher energy level of PET radiopharmaceutical activity (511 vs 140 keV for technetium) provides markedly improved image quality due to higher spatial resolution, less scatter, and common use of attenuation correction. These factors improve image quality and

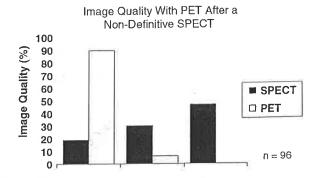


Figure 1. Comparison of image quality in patients undergoing SPECT and PET imaging. Adapted from Yoshinaga et al².

markedly reduce attenuation artifact. Image quality was recently studied by Yoshinaga et al² in which patients with equivocal SPECT studies were referred for cardiac PET imaging. In very high percentage of patients, the PET study patient resulted in good to excellent image quality, 90% for PET, 20% for SPECT (Figure 1). In that study, there was an obvious referral bias, but still demonstrated striking differences in quality in the same patient. Using a comparison of similar but matched patients undergoing SPECT or PET, Bateman, et al³ also reported a significant improvement in image quality with PET.

Attenuation artifact has been a major interpretation challenge for SPECT imaging. Because of the higher imaging activity of the radiopharmaceutical tracer as well as attenuation correction, PET imaging is far less susceptible to attenuation artifact. A recent study by Bateman et al³ evaluated artifact a similar group of SPECT and PET patients. As shown in Table 4 the incidence of significant artifact was reduced as well as gut uptake and particularly that in which interpretation could be compromised. A common reason for PET imaging inconclusive studies is that of an inconclusive

Table 4. Comparison of artifact between SPECT and PET perfusion imaging

	SPECT	PET	P value
No artifact	19 (17%)	49 (44%)	.0001
Minor artifact	26 (23%)	28 (25%)	.75
Significant artifact	64 (57%)	33 (29%)	.0003
Major artifact	3 (3%)	2 (2%)	.32
No GI uptake	45 (40%)	100 (89%)	<.001
Minor GI uptake	19 (17%)	5 (4%)	.0002
Significant GI uptake	46 (41%)	6 (5%)	<.001
Major GI uptake	2 (2%)	1 (1%)	.32

SPECT, Single photon emission computed tomography; PET, positron emission tomography; GI, gastrointestinal (Bateman et al³).

ORIGINAL ARTICLES

Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: Comparison with ECG-gated Tc-99m sestamibi SPECT

Timothy M. Bateman, MD, abc Gary V. Heller, MD, PhD, A. Iain McGhie, MD, Chip, John D. Friedman, MD, James A. Case, PhD, Lan R. Bryngelson, BN, Ginger K. Hertenstein, CNMT, Kelly L. Moutray, MEd, Kimberly Reid, MS, and S. James Cullom, PhDbc

Background. Although single photon emission computed tomography (SPECT) and positron emission tomography (PET) myocardial perfusion imaging (MPI) have evolved considerably over the last decade, there is no recent comparison of diagnostic performance. This study was designed to assess relative image quality, interpretive confidence, and diagnostic accuracy by use of contemporary technology and protocols.

Methods and Results. By consensus and without clinical information, 4 experienced nuclear cardiologists interpreted 112 SPECT technetium-99m sestamibi and 112 PET rubidium-82 MPI electrocardiography (ECG)—gated rest/pharmacologic stress studies in patient populations matched by gender, body mass index, and presence and extent of coronary disease. The patients were categorized as having a low likelihood for coronary artery disease (27 in each group) or had coronary angiography within 60 days. SPECT scans were acquired on a Cardio-60 system and PET scans on an ECAT ACCEL scanner. Image quality was excellent for 78% and 79% of rest and stress PET scans, respectively, versus 62% and 62% of respective SPECT scans (both p < .05). An equal percent of PET and SPECT gated images were rated excellent in quality. Interpretations were definitely normal or abnormal for 96% of PET scans versus 81% of SPECT scans (p = .001). Diagnostic accuracy was higher for PET for both stenosis severity thresholds of 70% (89% vs 79%, p = .03) and 50% (87% vs 71%, p = .003) and was higher in men and women, in obese and nonobese patients, and for correct identification of multivessel coronary artery disease.

Conclusion. In a large population of matched pharmacologic stress patients, myocardial perfusion PET was superior to SPECT in image quality, interpretive certainty, and diagnostic accuracy. (J Nucl Cardiol 2006;13:24-33.)

Key Words: Single photon emission computed tomography • positron emission tomography • myocardial perfusion imaging

See related article, p. 2

From Cardiovascular Consultants, PC,^a Cardiovascular Imaging Technologies, LLC,^b and Mid America Heart Institute,^c Kansas City, Mo, Division of Cardiology, Henry Low Heart Center, Hartford Hospital, Hartford, Conn,^d and Cedars-Sinai Medical Center, Los Angeles, Calif.^e

This work was supported in part by a grant from Bracco Diagnostics, Princeton, NJ.

Received for publication Apr 7, 2005; final revision accepted Sept 8, 2005.

Reprint requests: Timothy M. Bateman, MD, Cardiovascular Consultants, PC, 4320 Wornall Rd, Suite 2000, Kansas City, MO 64111; tbateman@cc-pc.com.

1071-3581/\$32.00

Copyright © 2006 by the American Society of Nuclear Cardiology. doi:10.1016/j.nuclcard.2005.12.004

Radionuclide myocardial perfusion imaging (MPI) is performed worldwide for assessing patients with known or suspected coronary artery disease (CAD). Most commonly, either thallium-201 or a technetium-99m perfusion tracer is used via single photon emission computed tomography (SPECT). An alternative is myocardial perfusion positron emission tomography (PET) using either cyclotron-produced ammonia or generator-produced rubidium 82. There are several potential advantages of PET MPI, such as higher spatial resolution, greater counting efficiencies, and robust attenuation correction. All of these factors presumably form the basis of improved diagnostic accuracy in comparison to SPECT in studies performed more than a decade ago. ²⁻⁶ Although these studies were instrumental in shaping

Impact of Myocardial Perfusion Imaging with PET and ⁸²Rb on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management

Michael E. Merhige^{1,2}, William J. Breen^{†1,3}, Victoria Shelton², Teresa Houston³, Brian J. D'Arcy^{1,3}, and Anthony F. Perna¹

¹Departments of Cardiology, Internal Medicine, and Nuclear Medicine, State University of New York at Buffalo, Buffalo, New York; ²Heart Center of Niagara, Niagara Falls, New York; and ³Buffalo Cardiology and Pulmonary Associates, Buffalo, New York

We hypothesized that PET myocardial perfusion imaging with 82Rb (PET MPI), would reduce downstream utilization of diagnostic arteriography, compared with SPECT, in patients matched for pretest likelihood of coronary disease (pCAD). PET MPI is more accurate for assessment of impaired coronary flow reserve compared with SPECT MPI, potentially reducing the demand for subsequent arteriography, percutaneous transcoronary intervention, and coronary artery bypass grafting (CABG), with attendant cost savings, while avoiding a negative impact on coronary events. Methods: The frequency of diagnostic arteriography, revascularization, costs, and 1-y clinical outcomes in 2,159 patients studied with PET MPI was compared with 2 control groups studied with SPECT MPI matched to the PET group by pCAD: an internal control group of 102 patients and an external SPECT control group of 5,826 patients. CAD management costs were approximated with realistic global fee estimates. Results: Arteriography rates were 0.34 and 0.31 for the external and internal control SPECT groups and 0.13 for the patients studied with PET (P < 0.0001). pCAD averaged 0.39 in patients studied with PET MPI, and in the external SPECT control group, and 0.37 in the internal SPECT controls. Revascularization rates were 0.13 and 0.11 for external and internal SPECT patients and 0.06 for the PET group (P < 0.0001; P < 0.01), with a cost savings of 30% noted for PET patients, with no significant difference in cardiac death or myocardial infaction at 1-y follow-up. Conclusion: PET MPI in patients with intermediate pCAD results in a >50% reduction in invasive coronary arteriography and CABG, a 30% cost savings, and excellent clinical outcomes at 1 y compared with SPECT.

J Nucl Med 2007; 48:1069–1076 DOI: 10.2967/jnumed.106.038323

ompelling evidence has demonstrated that invasive procedures such as coronary arteriography, coronary artery bypass grafting (CABG), and percutaneous transcoronary intervention (PTCI) are overutilized in the United States, contributing to unnecessary health care expense without improved patient outcomes (1-6). Management of coronary disease (CAD) currently utilizes noninvasive diagnostic testing as a "gatekeeper," which typically provokes invasive coronary arteriography when results are abnormal, to provide a definitive diagnosis of CAD. Thereafter, mechanical myocardial revascularization is usually performed on the basis of the coronary lumenogram, often without improved outcome-specifically in the hard endpoints of coronary death and myocardial infarction (MI)-despite great cost (7). Previous theoretic models have indicated that increased diagnostic accuracy of noninvasive testing, specifically myocardial perfusion imaging using PET (PET MPI), may reduce costs and improve outcomes when used in place of SPECT (SPECT MPI), in the routine management of CAD (8,9), however, documentation of this hypothesis in a prospective trial has not been previously reported.

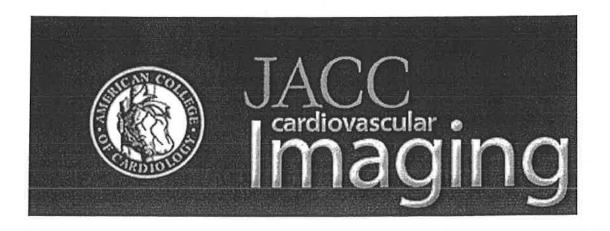
This study tests the hypothesis that a noninvasive strategy for CAD management using MPI, free of attenuation artifacts with improved resolution and image contrast due to substantially higher counts provided by PET, lowers costs of CAD management, through reduction of unnecessary downstream invasive diagnostic and therapeutic procedures, compared with conventional management with standard exercise SPECT, because of the improvement in diagnostic accuracy provided by PET.

In this study, clinical outcomes, procedure utilization, and costs were evaluated in 2,159 sequential patients imaged with PET MPI and compared with 2 control groups of patients, matched for pretest likelihood of CAD (pCAD), who were imaged with SPECT MPI.

Received Dec. 8, 2006; revision accepted Apr. 17, 2007. For correspondence or reprints contact: Michael E. Merhige, MD, Heart Center of Niagara, 521 Tenth St., Niagara Falls, New York 14302. E-mail: merhige@buffalo.edu

[†]Deceased

COPYRIGHT © 2007 by the Society of Nuclear Medicine, Inc.



Incremental Prognostic Value of Gated Rb-82 Positron Emission Tomography Myocardial Perfusion Imaging Over Clinical Variables and Rest LVEF Sharmila Dorbala, Rory Hachamovitch, Zelmira Curillova, Deepak Thomas, Divya Vangala, Raymond Y. Kwong, and Marcelo F. Di Carli J. Am. Coll. Cardiol. Img. 2009;2;846-854 doi:10.1016/j.jcmg.2009.04.009

This information is current as of July 14, 2009

The online version of this article, along with updated information and services, is located on the World Wide Web at: http://imaging.onlinejacc.org/cgi/content/full/2/7/846



Incremental Prognostic Value of Gated Rb-82 Positron Emission Tomography Myocardial Perfusion Imaging Over Clinical Variables and Rest LVEF

Sharmila Dorbala, MD,*† Rory Hachamovitch, MD, MSc,‡ Zelmira Curillova, MD,*† Deepak Thomas, MD,* Divya Vangala,* Raymond Y. Kwong, MD,† Marcelo F. Di Carli, MD*† Boston, Massachusetts; and Los Angeles, California

OBJECTIVES This investigation sought to study the incremental value of gated rubidium (Rb)-82 positron emission tomography (PET) myocardial perfusion imaging (MPI) over clinical variables for predicting survival and future cardiac events.

BACKGROUND The prognostic value of Rb-82 PET-MPI and left ventricular ejection fraction (LVEF) reserve (stress minus rest LVEF) is not well defined.

METHODS 1,432 consecutive patients undergoing gated rest/vasodilator stress rubidium-82 PET were followed up for at least 1 year. Of these, rest and peak stress LVEF and LVEF reserve were available in 985 patients. Cardiac events (CE) including cardiac death or nonfatal myocardial infarction and all-cause death were assessed.

RESULTS Over a mean follow-up of 1.7 ± 0.7 years, 83 (5.8%) CE and 140 (9.7%) all-cause death were observed. There was an increase in risk for both end points with an increasing percentage of abnormal and ischemic myocardium. With normal, mild, moderate, or severely ischemic scans, the observed annualized rates of CE were 0.7%, 5.5%, 5%, and 11% and of all-cause death were 3.3%, 7.2%, 6.9%, and 12.5%, respectively. In 985 patients with peak stress gated data, the observed annualized rates of CE (2.1% vs. 5.3%, p < 0.001) and all-cause death (4.3% vs. 9.2%, p < 0.001) were higher in patients with an LVEF reserve <0% compared with those with an LVEF reserve \geq 0%. On Cox proportional hazards analysis, after consideration of clinical, historical, and rest LVEF information, stress PET results and LVEF reserve yielded incremental prognostic value with respect to both CE and all-cause death.

CONCLUSIONS Vasodilator stress Rb-82 PET-MPI provides incremental prognostic value to historical/clinical variables and rest LVEF to predict survival free of CE and all-cause death. An increasing percentage of ischemia on PET-MPI is associated with an increase in the risk of CE and all-cause death. Left ventricular ejection fraction reserve provides significant independent and incremental value to Rb-82 MPI for predicting the risk of future adverse events. (J Am Coll Cardiol Img 2009;2:846–54) © 2009 by the American College of Cardiology Foundation

From the *Division of Nuclear Medicine and Molecular Imaging, Department of Radiology, and the †Noninvasive Cardiovascular Imaging Program, Departments of Medicine (Cardiology) and Radiology, Brigham and Women's Hospital, Boston, Massachusetts; and from ‡Los Angeles, California. Dr. Dorbala is a member of the Speakers' Bureau for Astellas and has received speaking honoraria from Bracco Diagnostics. Dr. Hachamovitch is a member of the Speakers' Bureau for Bracco Diagnostics and has received research grants from GE Healthcare. Dr. Di Carli has received research grants from GE Healthcare, Bracco Diagnostics, Siemens, and Astellas; is a member of the Speakers' Bureau for Bracco Diagnostics; and is a Consultant/Advisory Board member for Bracco Diagnostics.

Manuscript received September 8, 2008; revised manuscript received April 7, 2009, accepted April 30, 2009.

ercise, or dobutamine PET studies because of inherent differences in baseline patient risk and levels and duration of peak coronary flow achieved.

CONCLUSIONS

The percentage of ischemic myocardium on vasodilator stress Rb-82 PET-MPI is a powerful predictor of CE and survival in patients with known CAD or an intermediate to high pre-test likelihood of CAD. Rb-82 PET-MPI provides significant incremental value over the baseline clinical variables, rest LVEF and stress data. The addition of LVEF reserve provides significant independent and incremental value to Rb-82 MPI for stratifying risk of future serious adverse events.

Acknowledgments

The authors thank Shawn Murphy and Henry Chueh and the Partners Health Care Research Patient Data Registry group for facilitating the use of their database.

Reprint requests and correspondence: Dr. Sharmila Dorbala, Brigham and Women's Hospital, Cardiovascular Faculty Offices, Shapiro 5, Room 128, 70 Francis Street, Boston, Massachusetts 02115. E-mail: sdorbala@partners.org.

REFERENCES

- 1. Di Carli MF, Hachamovitch R. New technology for noninvasive evaluation of coronary artery disease. Circulation 2007;115:1464–80.
- Sampson UK, Dorbala S, Limaye A, Kwong R, Di Carli MF. Diagnostic accuracy of rubidium-82 myocardial perfusion imaging with hybrid positron emission tomography/computed tomography in the detection of coronary artery disease. J Am Coll Cardiol 2007; 49:1052-8.
- Dorbala S, Vangala D, Sampson U, Limaye A, Kwong R, Di Carli MF. Value of vasodilator left ventricular ejection fraction reserve in evaluating the magnitude of myocardium at risk and the extent of angiographic coronary artery disease: a 82Rb PET/CT study. J Nucl Med 2007;48:349-58.
- 4. Go RT, Marwick TH, MacIntyre WJ, et al. A prospective comparison of rubidium-82 PET and thallium-201 SPECT myocardial perfusion imaging utilizing a single dipyridamole stress in the diagnosis of coronary artery disease. J Nucl Med 1990;31:1899-905.
- 5. Stewart RE, Schwaiger M, Molina E, et al. Comparison of rubidium-82 positron emission tomography and thallium-201 SPECT imaging for detection of coronary artery disease. Am J Cardiol 1991;67:1303-10.
- Bateman TM, Heller GV, McGhie AI, et al. Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: comparison with ECGgated Tc-99m sestamibi SPECT. J Nucl Cardiol 2006;13:24–33.
- Merhige ME, Breen WJ, Shelton V, Houston T, D'Arcy BJ, Perna AF. Impact of myocardial perfusion imag-

- ing with PET and (82)Rb on downstream invasive procedure utilization, costs, and outcomes in coronary disease management. J Nucl Med 2007; 48:1069–76.
- Yoshinaga K, Chow BJ, Williams K, et al. What is the prognostic value of myocardial perfusion imaging using rubidium-82 positron emission tomography? J Am Coll Cardiol 2006; 48:1029-39.
- Marwick TH, Shan K, Patel S, Go RT, Lauer MS. Incremental value of rubidium-82 positron emission tomography for prognostic assessment of known or suspected coronary artery disease. Am J Cardiol 1997;80: 2017.
- 10. Sdringola S, Loghin C, Boccalandro F, Gould KL. Mechanisms of progression and regression of coronary artery disease by PET related to treatment intensity and clinical events at long-term follow-up. J Nucl Med 2006;47:59-67.
- 11. Hachamovitch R, Hayes SW, Friedman JD, Cohen I, Berman DS. Comparison of the short-term survival benefit associated with revascularization compared with medical therapy in patients with no prior coronary artery disease undergoing stress myocardial perfusion single photon emission computed tomography. Circulation 2003;107:2900-7.
- 12. Cox DR. Regression models and lifetables (with discussion). J R Stat Soc Ser 1972:187–220.
- Greenland S. Modeling and variable selection in epidemiologic analysis. Am J Public Health 1989;79:340–9.
- 14. Pryor DB, Shaw L, McCants CB, et al. Value of the history and physical in identifying patients at increased risk

- for coronary artery disease. Ann Intern Med 1993;118:81-90.
- 15. Hachamovitch R, Berman DS, Morise AP, Diamond GA. Statistical, epidemiological and fiscal issues in the evaluation of patients with coronary artery disease. QJ Nucl Med 1996;40: 35–46.
- 16. Di Carli MF, Dorbala S, Meserve J, El Fakhri G, Sitek A, Moore SC. Clinical myocardial perfusion PET/ CT. J Nucl Med 2007;48:783–93.
- Schwaiger M, Ziegler S, Nekolla SG. PET/CT: challenge for nuclear cardiology. J Nucl Med 2005;46:1664–78.
- 18. Hachamovitch R, Rozanski A, Hayes SW, et al. Predicting therapeutic benefit from myocardial revascularization procedures: are measurements of both resting left ventricular ejection fraction and stress-induced myocardial ischemia necessary? J Nucl Cardiol 2006;13:768–78.
- 19. Lertsburapa K, Ahlberg AW, Bateman TM, et al. Independent and incremental prognostic value of left ventricular ejection fraction determined by stress gated rubidium 82 PET imaging in patients with known or suspected coronary artery disease. J Nucl Cardiol 2008;15:745–53.
- Brown TL, Merrill J, Volokh L, Bengel FM. Determinants of the response of left ventricular ejection fraction to vasodilator stress in electrocardiographically gated (82)rubidium myocardial perfusion PET. Eur J Nucl Med Mol Imaging 2008;35:336-42.

Key Words: prognosis ■ imaging ■ tomography.

the source for radiology professionals

Where Quality Counts

A preview of RSNA's 95th COUNTS scientific assembly and annual meeting

PLUS

- An Alternative to Mo-99
- CARE Bill Update
- Eco-Conscious Vendors

A Conversation with . . . Kim Giordano, CNMT

Bracco's solution to the Mo-99 isotope crisis

MOLYBDENUM-99 (MO-99) IS THE PRECURSOR FOR TECHNETIUM-99M, a radioisotope used in 80 percent of diagnostic and nuclear medicine procedures. However, earlier this year, following an unexpected shutdown at the Canadian nuclear reactor that provides 50 percent of the Mo-99 supply in the U.S., the nuclear medicine industry has been dealt a massive blow in the form of possible shortages.

Only a handful of facilities around the world can generate quantities of Mo-99 that can be exported for commercial use – of those five reactors, three are in Europe, one is in Canada, and one is in South Africa. Since these medical isotopes cannot be stockpiled, disruptions at even one of those facilities can quickly affect the chain of supply to the entire industry, leaving today's healthcare professionals grasping for solutions.







Unfors Instruments, Inc. 48 Anderson Avenue, Suka 1 New Millord, CT 06776, USA Phone: (866) 4UNFOR: +1 (860) 355-258: Fax: +1 (860) 350-266: E-mail: Info@undors.com One company – Princeton, N.J.-based Bracco Diagnostics Inc. – believes it has developed a viable solution to ease the strain of impending Mo-99 shortages with CardioGen-82, the only generator-based, cardiac PET perfusion imaging agent approved by the FDA. **rt image** sits down with Kim Giordano, Bracco's vice president of corporate accounts and nuclear medicine, as well as a certified nuclear medicine technologist, to discuss what relief this product is expected to bring to the Mo-99 shortage.

Qrtimage: How does PET Myocardial Perfusion Imaging (MPI) provide a long-term solution to the current Mo-99 crisis?

A Kim Giordano: Since CardioGen-82® (Rubidium Rb-82 Generator) is not reliant upon the supply of Mo-99, it has much greater availability for use in performing nuclear cardiology studies. Many centers that are experiencing difficulty obtaining the isotopes used for MPI with SPECT also have access to a PET scanner. Using PET instead of SPECT for MPI has many clinical and logistical advantages. Now cardiac PET with CardioGen-82 offers even more benefits because patient studies no longer have to be postponed or canceled due to the Mo-99 shortage. Facilities that offer PET MPI as part of their cardiac imaging service can continue to maintain and expand their nuclear cardiology patient volumes.

Q and logistically, for CAD patients and interpreting physicians?

A Giordano: PET images provide more than twice as many photon counts as SPECT images. This, combined with improved spatial resolution and attenuation correction on all scans, enhances the overall image quality and diagnostic accuracy. CardioGen-82 PET offers imagers greater interpretive certainty versus SPECT – 96 percent versus 82 percent respectively. Moreover, typical PET MPI protocols are completed (gated rest and stress) in 30 minutes to 45 minutes, instead of about three hours with SPECT. Therefore, PET provides both clinical and logistical advantages for CAD patients and interpreting physicians.

Qimage: Are there any patients who would not benefit from a cardiac PET study, or are there contraindications to the test?

A Giordano: CardioGen-82 has no known contraindications.
According to Medicare, PET is reimbursed for many of the

SUPPORT LETTERS

AFFIDAVIT 2013 APR 15-ECRIME AT CARDIOCOGY SERVICES

STATE OFTENNESSEE
COUNTY OFDAVIDSON
JOHN WELLBORN, being first duly sworn, says that he/she is the lawful agent of the applicant named in this application, that this project will be completed in accordance with the application to the best of the agent's knowledge, that the agent has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, et seq., and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete to the best of the agent's knowledge.
$\bigcap A \cap A$
SIGNATURE/TITLE
Sworn to and subscribed before me this 15 day of April , 2013 a Notary
Public in and for the County/State of
MOTARY PUBLIC
My commission expires(-21

COPY-

SUPPLEMENTAL-1

Wellmont Cardiology Services, Inc.

CN1304-013

DSG Development Support Group

SUPPLEMENTAL

2013 APR 26 PH 1: 23

April 26, 2013

Phillip M. Earhart, Health Planner III
Tennessee Health Services and Development Agency
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37203

RE:

CON Application CN1304-013

Wellmont Cardiology Services, Inc.

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. A second response letter under separate cover will be sent for a few questions, as indicated. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. Section A, Applicant Profile, Item 2
Please provide a complete contact phone number.

Revised page 1R is attached following this page with the omitted digit corrected. Revised page 2R is also attached, showing in item 7(a) that the project will establish an ODC if such licensure is later required under State law. This makes item 7(a) consistent with the legal notice.

2. Section A, Applicant Profile, Item 6

Please provide a lease or option to lease agreement that includes the actual/anticipated term of the agreement and actual/anticipated lease expense.

The applicant currently has control of the project site through the Wellmont Health System Lease Agreement in Attachment A.6. Page five of that lease, in its last paragraph, states that WCS may use the leased building. There are no new lease costs required for the calculation of project costs.

3. Section B, Project Description, Item I

a. The applicant states the proposed Cardiac PET location will be 10.6 miles from its current location in Gray, TN. Please clarify if this is a straight line measurement or measured by driving distance.

That was the driving distance stated by the Google Maps website.

Page Two April 26, 2013

b. The applicant states the proposed project does not add an additional PET unit to the area, or a new service to the area or to Sullivan County.

If this is correct, please clarify why this proposed service area is different from the original application of CN0701-010, LifeScan Tennessee, LLC, from whom the applicant plans to purchase a PET/CT.

The originally approved service area of LifeScan Tennessee, LLC consisted of ten (10) Tennessee Counties, including Carter, Cocke, Greene, Hamblen, Hancock, Hawkins, Johnson, Sullivan, Unicoi and Washington Counties.

The Tennessee service area of this project is the same as the Tennessee service area projected in the 2007 application--when you compare this project's primary and secondary Tennessee service area counties to the ten counties that were that earlier project's primary and secondary service area.

The 2007 application described its ten-county Tennessee service area as its Tennessee "primary" service area.

But on page 3 of the application's January 26, 2007 supplemental responses, the applicant's more detailed patient origin data demonstrated that those Tennessee counties would generate between 93% and 100% of the PET's total Year One utilization of 690 procedures. So that made the ten Tennessee counties its <u>primary plus secondary</u> Tennessee service area.

The WCS application now under review listed only its <u>primary</u> Tennessee service area counties. To compare apples to apples, you must consider WCS's <u>primary and secondary</u> Tennessee service area counties. They are provided below, in Table Six (Supplemental). Please note that WCS does, and will, serve the same ten Tennessee counties listed in the 2007 LifeScan application. No other Tennessee county will generate even one-tenth of one percent of the WCS utilization.

Page Three April 26, 2013

Table Six (Sup	pnlemental)
Consistency of Tennessee Primary &	
CN0710-01 (Gray Cardiac PET ODC) vs	. Wellmont Cardiology Services PET
Tennessee Service Area Counties Projected In	CY2014 Percent of Total
Approved CN0701-10	WCS Cardiac PET Patients
for Molecular Imaging Alliance ODC, Gray	from That County
1. Carter	2.6%
2. Greene	7.3%
3. Hawkins	8.0%
4. Johnson	0.8%
5. Sullivan	26.8%
6. Unicoi	1.7%
7. Washington	8.4%
8. Cocke	0.1%
9. Hamblen	0.2%
10. Hancock	0.3%
All Other TN Counties (13) each <1/10 th of 1%	0.4%
Other States	43.4%
Total WCS Cardiac PET Service Area	100%

Source: CN0710-01; WCS management.

c. The provider, Molecular Imaging Alliance, CN1304-014, has filed a companion application that proposes a service area consisting of five (5) Tennessee counties that includes Carter, Greene, Sullivan, Unicoi and Washington counties. The applicant, Wellmont Cardiology Services, Inc., proposes to change the service area by adding Hawkins County but exclude Unicoi and Carter counties to the proposed service area. Please clarify the reason why there is now a new service area especially while the applicant states the proposed project will not serve any of the Tennessee counties not already being served by the cardiac PET ODC in Gray.

Supplemental data submitted this week for Molecular's CN1304-014 application shows that its Tennessee primary and secondary service area counties do include 70% (seven of ten) of the Tennessee counties projected in its 2007 application-and more importantly, that the seven being served include 82% of the population of the earlier projected ten-county area. That is substantial compliance with the original projection. Please note that except for hospice/home health projects, CON approvals do not authorize, or require, that specific counties be served. They approve a specific provider and a specific service at a specific location--with an implicit reasonable expectation that this will provide service to the counties projected. The Molecular ODC at its current and proposed sites clearly do what

Page Four April 26, 2013

was originally intended, which is to serve as much of Upper East Tennessee as possible. It should be significant that the proposed "splitting" of the originally approved PET service into two new locations, closer to patients and referring physicians, will make the service more accessible to all ten of the counties originally targeted for service in the 2007 application.

d. The applicant mentions SPECT testing and the discouragement of its use by WCS patients and cardiologists. Please describe a SPECT test and the name and location of the provider who offers this service and the reason for the discouragement of its use. Why do cardiologists need to go and supervise the SPECT test?

SPECT is an acronym for "single photon emission computed tomography". It is a nuclear medicine test, a type of radionuclide imaging, by which any areas of the body can be studied through studying the movement and destination of a slightly radioactive substance.

SPECT is performed with a wide variety of injected radiopharmaceuticals, and with many different types of SPECT equipment. It is provided in almost every cardiology group in the country, according to WCS. For example, WCS has multiple SPECT units already accessible in The Heart Center, which are operated as Holston Valley Medical Center outpatient services. Attached at the end of this letter is a print from Wikepedia providing a simplified explanation of SPECT.

SPECT is an excellent diagnostic test. It is not being discarded in favor of cardiac PET tests. But for patients with large body mass on and around the part of the body to be studied, cardiac PET is clearly superior to SPECT. That group is a significant percentage of patients. But again, as the applicant's projection methodology showed, only a portion of current SPECT patients will be "converted" to cardiac PET or supplemented with a cardiac PET. Please see the medical literature the applicant submitted in the original application.

Cardiologists must be present during cardiac SPECT and PET studies because of the risk of patient cardiac arrest during the "stress" part of the test--which involves pharmacologically accelerating the patient's heart rate as if in a demanding treadmill test. Approximately 90% of cardiac SPECT studies involve stressing the heart.

Page Five April 26, 2013

e. What is the applicant's historical utilization (last three years) of SPECT procedures?

Procedure	Location	CY2010	CY2011	CY2012
	WCS offices, WCS ordered			
SPECT studies	tests at Wellmont hospitals	5,906	7,285	7,835

Source: WCS Management

f. The patient mentions 1,500 patients would benefit from cardiac PET testing. If this is the case, where are these 1,500 patients now receiving cardiac PET services?

These 1,500 patients are not receiving cardiac PET services now. They are the current WCS SPECT patients who, being larger in body mass, (1) would benefit from having cardiac PET instead of cardiac SPECT, or (2) need a PET follow-up after an inconclusive or ambiguous SPECT test.

See also revised page 32R, attached after this page. These patients cannot gain access to cardiac PET on Holston Valley's mobile PET because that service allows only six cardiac test patients a week (300 patients/year) due to its high utilization and the need to give priority to oncology patients. The Gray unit is not a viable alternative because, after trying to use it when it first began operation, WCS found that the requirement of having the cardiologist on-site at Gray prevented their cardiologists from being able to provide other important patient care services simultaneously (a problem that will not occur when the cardiac PET is located within the Kingsport office of the WCS cardiologists).

g. How many patients of WCS received cardiac catheterizations and coronary artery bypass grafts in 2012?

Procedure	Location	CY2010	CY2011	CY2012
Diagn. Cardiac Cath	HolstonValley Med Center	2,263	2,388	2,408
CABG (bypass surgery)	HolstonValley Med Center	271	200	195

Source: WCS Management

1:15 pm

Page Six April 26, 2013

h. The applicant states the availability of the service for this region has received CON approval already. Please discuss how many PET scanners were granted to the provider Lifescan Tennessee, LLC in the application, CN0701-010A and if an additional Certificate of Need was needed for the 2nd Cardiac PET unit that the applicant proposes to purchase.

CN0701-010A granted LifeScan Tennessee authority to initiate cardiac PET services by acquisition of one PET system.

No CON was needed to add the second PET unit in 2008. First, because there was no such condition imposed on that CON. Second, because the CON statute did not require any existing PET provider to obtain CON approval for an additional PET system whose cost or fair market value was below \$1,500,000 (the review threshold in 2008). Attached following this page is a letter documenting that the second LifeScan PET system's fair market value was far below the capital review threshold for additional major medical equipment.

Both cardiac PET systems are properly in operation for the purposes of the CON program. The applicant believes that the HSDA therefore should not consider the second installed system as a "new" or "additional" system if it must be reviewed under the State Health Plan CON standards and criteria for PET.

i. Does the applicant have ownership or interest in the cyclotron (Precision Nuclear, LLC) located in Gray, Tennessee?

No.

j. Are there additional cyclotrons in the proposed service area? If so, please identify the name and location.

There are no other cyclotrons east of Knoxville.

k. The applicant states Molecular Imaging Alliance, CN1304-014 is a companion project. Does the applicant have ownership in Molecular Imaging Alliance?

No.

SOTER A Imaging Services LL22

April 22, 2013

Melanie Hill, Executive Director
Tennessee Health Services and Development Agency
Frost Building, Third Floor
161 Rosa Parks Boulevard
Nashville, Tennessee 37203

RE: Siemens Cardiac PET Unit

LifeScan Tennessee Outpatient Diagnostic Center at Gray

Dear Mrs. Hill:

Robert Gregory, the current owner of Lifescan LLC, has asked me to confirm the fair market value of the subject Cardiac PET system which Soteria Imaging transferred to LifeScan Tennessee in May, 2008 at the time Soteria owned LifeScan Tennessee.

The unit was purchased new by Soteria in June of 2002. It was almost six years old when transferred to the books of our Gray facility in May 2008. The depreciated, or net book value of the unit at the time of transfer was \$150,000. Neither Soteria nor LifeScan had a service or maintenance contract with a third party for that system; service when needed was provided by Soteria personnel and the cost of that was charged to LifeScan.

I am told that this transfer of a second system into our Gray facility did not require CON approval if the value of the system and any maintenance contract were less than \$1.5 million at the time. The book value of this used system was obviously much less; and I estimate that its actual market value would not have been even as high as \$500,000.

Sincefely,

Richard G. Taylor

Chief Financial Officer

Page Seven April 26, 2013

4. Section B, Project Description, Item II.A. a. Please describe the nuclear "hot lab".

A nuclear hot lab for PET is a single room where (a) the radioactive dose from the vendor is physically delivered, (b) the containers are validated by the nuclear medicine technician to be free of external radiation dangers, (c) the dosages are validated to comply with dosage requirements, and (b) the dosages are placed in shielded syringes, inside shielded containers, before transport to the "camera room" where the patient is lying on a table to receive the injection.

The hot lab room has a dose calibrator, a lead-shielded PET unit dose cabinet, meters with probes, a lead L-block shield, leaded syringe carriers and shields, and various support items such as instruments, decontamination kit, sharps containers, and radioactive sources (200mci; 5 mci). The shielding protects the technician, nurse, physician, and patient--before, during, and after the injection of the radioactive substance in the adjoining cardiac PET camera room.

b. The applicant states a mobile PET/CT are readily available at Holston Valley Medical Center in Kingsport to Wellmont patients in Kingsport, TN. What is the distance and driving time from WCS's Heart Center office building to Holston Valley Medical Center in Kingsport. Is there an on-site cyclotron that supplies radiopharmaceuticals to the mobile PET/CT service at Holston Valley Medical Center? How many Wellmont patients are currently referred to the Holston Valley Medical Center for cardiac PET procedures?

There is no cyclotron at Holston Valley Medical Center or any other location in Upper East Tennessee other than at Gray.

The roadway distance and drive time from the project site on Meadowview Parkway, to the Holston Valley Medical Center campus, is 4.3 miles and 12 minutes, according to Google Maps.

Currently WCS is allowed to schedule only six (6) patients per week on the mobile service (equates to only 300 annually on a 50-week year), so that the mobile service can remain devoted primarily to oncology studies. WCS patients are backlogged for service now, facing a two-month wait for access to service on the mobile PET.

Page Eight April 26, 2013

c. Please clarify if there is a difference between the quality of a cardiac/PET procedure conducted at a fixed/PET versus a mobile PET. Are there any other differences?

There is no difference. The advantages of the fixed PET to WCS patients are that (1) it would be available daily, at the cardiology office where most of them now go, and (2) that it would eliminate their waiting time for this important test.

d. Does this proposed project include an on-site cyclotron? If not, are there any long-term plans to include a cyclotron on-site?

It does not include an on-site cycloton. Nor are there any plans for one. The cyclotron in Gray provides excellent service to Wellmont. The applicant has no reason to incur such a large expense for its own dedicated cyclotron.

e. Table Three-B on the bottom of page eleven is noted. The correct CON number for ImagDent of Memphis is CN0908-044. Please revise and submit a replacement page.

Revised page 11R is attached following this page, with the extra mistyped digit removed from that number.

5. Section B, Item II.C.

The applicant states it has not been feasible to refer patients to Gray Tennessee for two reasons: 1) many people prefer to have all their testing needs met in one continuum 2) a cardiac PET study requires a cardiologist to spend several hours a day in Gray conducting cardiac PET studies. The applicant mentions referring patients to Gray, Tennessee and to Holston Valley Medical Center. Does the applicant also send cardiologists to Holston Valley in the same manner as reported for the cardiac/PET unit in Gray, Tennessee.

Yes. When a patient has this procedure at Holston Valley Medical Center it is supervised at that location by the WCS cardiologist who is on-site that day, or who is assigned to go to the site.

Page Nine April 26, 2013

6. Section B, Item II. D.

In the companion application, Molecular Imaging Alliance, CN1304-014, the applicant states cardiac PET uses only two radiopharmaceuticals: ammonia (N-13) or rubidium (R-82). The applicant states N-13 has a half-life of 10 minutes and R-82 has a half-life of 75 seconds. The applicant further states as a practical matter, the radiopharmaceutical supplier must be within a short drive of the cardiac PET, if not in the same building (such as the The applicant states the current current case for the applicant). radiopharmaceutical provider will continue to provide materials by manufacturing sufficient amounts so that the required dosage is sufficient by the time it is administered. The applicant states if the delivery trip time plus administration of the pharmaceutical takes 30 minutes, then the amount with the strength of eight doses of N-13 might be sent, so that after its radioactivity diminishes by 50% every 10 minutes, one full doses remains for injection. Please respond to the following questions in regards to the above statements:

a. Is the situation as described above in the companion application also going to be experienced by this applicant since there is a similar distance from the cyclotron in Gray, TN?

Yes, it is.

b. On Table Eleven on page 43, the applicant assigns two doses of Nitrogen N-13 ammonia to each patient for the charge data in the amount of \$320.00 (\$160.00 per dose). Is the increase per dose, or approximately \$240,000 per year in cost (\$160.00 per dose times 1500 cases), attributed to the diminishing radioactivity of the doses as they are transported from the cyclotron in Gray, TN to the proposed site in Kingsport?

The cyclotron vendor at Gray will not charge the applicant more to ship additional amounts of the compound to Kingsport. Wellmont's mobile PET is already a customer of this vendor for its mobile service. The dosage prices in the application reflect current pricing, which the vendor has committed to hold.

The term "doses" needs clarification. Approximately 90% of WCS patients will be injected and tested at two times on the same day--once at rest and once with the heart stressed, with waiting time in between. The cyclotron delivers two actual doses of the radioactive N-13 ammonia, in two separate trips, for every patient being stress-tested. The stressed part of the test is pharmacologically-induced stress, from injection of a nonradioactive medication, Lexiscan, which WCS (not the cyclotron) has in its own practice pharmacy.

Page Ten April 26, 2013

c. What happens if there is a time delay during transport of radiopharmaceuticals?

The vendor has been delivering N-13 to the mobile PET at Holston Valley Medical Center in Kingsport for more than a year and has never been delayed sufficiently to require rescheduling of patients. According to the vendor, that delivery averages 23 minutes drive time one-way, compared to only 12 minutes to the WCS project site on Meadowview Parkway, and 13 minutes to the Molecular project site in Johnson City. In addition, the vendor's drivers constantly monitor emergency broadcast frequencies to identify road closures or automobile accidents, and they choose alternate routes to avoid such delays.

If there were a major delay, for example from a storm or emergency closure of an interstate or federal highway, the patient would be rescheduled. This is an outpatient diagnostic procedure.

d. Is it safer for the patient to receive radiopharmaceuticals from a cyclotron on-site where the time element is more closely monitored?

No, it is not. All delivery drivers must be licensed by the State Department of Conservation and Environment to handle radioactive materials and must be trained and certified by the US Department of Transportation in safe transport procedures. Off-site delivery is a safe and well-established practice nationally because cyclotrons are expensive and few in number, and they supply most of their customers through off-site deliveries across a wide service area.

7. Section B, Item II. E. What is the age of the proposed PET scanner?

It is approximately eleven years old. Soteria Imaging advises us that it was purchased new by another company in 2002. Soteria then acquired it and installed it in the Gray ODC when the ODC opened in late 2007. In 2011, ownership of both this GE sysem and the Siemens system were transferred by LifeScan Tennessee to Lifescan Leasing, at the direction of their common parent company, Soteria Imaging.

Page Eleven April 26, 2013

8. Section C, Need, Item 1. (Project-Specific Criteria: PET Scanners)
The proposed project is changing ownership, proposed service area and location. Please address the revised and Updated standards for Positron Emission Tomography (PET) services found in the State Health Plan.

These will be submitted under separate cover in a second response letter.

9. Section C, Need, Item 1. (Project-Specific Criteria: Outpatient Diagnostic Centers)

a. Item #1-Please address the need for outpatient diagnostic services by county projecting four years into the future using available population figures.

These will be submitted under separate cover in a second response letter.

b. The applicant displays a chart that indicates forty (40) patients were sent from Sullivan County in 2012 to Molecular Imaging Alliance in Gray, Tennessee. The applicant appears to be competing with the mobile PET at Holston Valley Medical Center and, if approved, the similarly proposed companion application Molecular Imaging Alliance, CN1304-014 that has an over-lapping service area with the applicant. Has the applicant considered conducting studies other than cardiac PET procedures such as cancer and Alzheimer's to meet the optimal efficiency for a stationary PET unit of 1,600 procedures per year?

Although Molecular Imaging Alliance and Wellmont Cardiology Services serve the same area, they will continue to have separate referral sources in the physician community; so their competition will be more theoretical than actual.

The applicant is dedicating this unit to its own patients, all of whom require cardiology studies and not cancer or neurological studies. As you can tell from the documentation of 1,500 annual scans in each of its first two years, this unit in its first year of operation will perform 1,500 procedures, almost at the 1,600-procedure standard for optimal utilization. So the applicant sees no need or even an opportunity to supplement its use with other types of studies, which are better performed on the several other PET/CT units in the service area.

Page Twelve April 26, 2013

c. The applicant has provided an attachment labeled, "C, Need—1A.3.e., Letters of Intent". Please clarify which section the applicant is referencing with this attachment.

That attachment contained a letter of intent from the cyclotron company attesting that it will provide the necessary dosages to the applicant's location, and a seller's letter of commitment documenting the applicant's stated purchase price for the PET system. These letters of documentation refer back to several sections of the application, including the Project Description in Section B.IIA, and the cost estimates in Section C(II)1.

d. The Attachment, "C, Need-1A.3e.", as listed above is a letter from Precision Nuclear, LLC stating the ability and intent to supply dosing for Cardiac PET perfusion imaging to CVA Heart Institute in Johnson City and Kingsport, TN. Please clarify the association of the applicant with the CVA Heart Institute locations in Johnson City and Kingsport, TN.

This letter is written to LifeScan. It states that the vendor will "supply your PET imaging system and the PET imaging system at CVA Heart Institute...at...Johnson City and Kingsport." The words "your PET imaging system" refer to LifeScan Tennessee, the addressee of the letter.

WCS, the applicant, is a physician group practice wholly owned by Wellmont Health System. Wellmont CVA Heart Institute is a name by which this specialty medical group is known. Wellmont Health System leases The Heart Center building in Kingsport, where the WCS group (the Wellmont CVA Heart Institute) has its main practice offices, and where WCS proposes to implement the project. WCS also has a satellite office in Johnson City.

10. Section C, Need, Item 3
The applicant refers to Table Six-Patient Origin Projection on page 27 which is missing. Please submit.

Please. The omitted page 27 is attached following this page. But please also see the Table Six (Supplemental) and narrative submitted in response to questions 3b-3c above.

Page Thirteen April 26, 2013

11. Section C, Need, Item 5

a. The applicant mentions the remote location of the current two PET scanners in Gray Tennessee is located between the region's two largest medical care centers. What are the names of the medical centers?

Wellmont Holston Valley Medical Center in Kingsport; and Mountain States Health Alliance's Johnson City Medical Center in Johnson City.

b. Please clarify if the location is Gray, TN for the two (2) PET scanners was originally strategically chosen to serve the two mentioned medical centers.

The original location in Gray was intended to serve patients from both the Kingsport and Johnson City medical centers. It has served hundreds of patients annually from that location. However, many more physicians and patients would utilize it, if it were closer to the physician and patient concentrations around the medical centers. The proposed locations have been chosen to provide that advantage. The Kingsport location is where the great majority of outpatient cardiology procedures are performed for Wellmont patients.

c. The applicant has provided table eight that displays utilization for Molecular Imaging Alliance Cardiac PET only. Please revise and include all PET units in the proposed service area and indicate if cardiac PET services are attached to each unit listed, and if the unit is fixed or mobile.

This will be provided under separate cover--except for information that is not publicly available or otherwise known to the applicant, on whether area PET's or PET/CT's other than Wellmont's own mobile system are equipped with the software package to perform cardiac studies.

12. Section C, Need, Item 6

When does the applicant expect to reach optimal capacity for PET (1600 procedures) per year according to the State Health Plan.

The applicant hopes to reach a rate of 1,600 cardiac PET procedures sometime in Year Three (CY2016).

Page Fourteen April 26, 2013

13. Section C. Economic Feasibility Item 1 (Project Cost Chart)

The applicant has listed \$2,410 as the CON filing fee on the Project Cost

Chart. Please revise with the correct CON filing fee and resubmit a revised Project Cost Chart.

That was not a calculation error. It was a rounding to the nearest dollar, of the exact figure of \$2,409.75. Applicants in the past have been allowed to so round off the fee not only on the Project Cost Chart but also in the actual filing fee check.

14. Section C. Economic Feasibility Item 2

Please provide "Attachment C, Economic Feasibility-2" that documents funding availability for the proposed project.

The letter is attached following this page.

15. Section C, Economic Feasibility, Item 4.

a. Please itemize "D.3 Supplies" located on the Projected Data Chart in the amounts of \$588,000 and \$605,640 for the Years 2014 and 2015, respectively.

Revised page 40R with supplies itemized will be forwarded under separate cover.

b. If the applicant had a cyclotron on-site what would be the impact on Project Costs and the Projected Data Chart?

This has not been calculated by the applicant. It would be financially unfeasible for WCS to undertake such a large capital investment (seven figures). No other party is likely interested in doing it. The existing cyclotron in Gray has a well-developed customer network in the region and WCS has no reason to change its cyclotron provider.

c. Please indicate if the cost of radiopharmaceuticals were factored in the Projected Data Chart.

They were factored into the supplies line. See response to your question 15a above.

Page Fifteen April 26, 2013

16. Section C, Economic Feasibility, Item 6.B.

Please submit Table Eleven (chart showing the most frequent procedures to be performed, with the current Medicare reimbursement, and their projected Year One and Year Two utilization and average gross charges.)

Revised page 43R is attached following this page.

17. Section C, Economic Feasibility, Item 10.

Please provide the mentioned financial statements listed as "Attachment C, Economic Feasibility—10".

They are attached following this page.

18. Section C, Orderly Development, Item 1.

The applicant states there are no shortage of working relationships between the applicant and any level of healthcare provider that might be needed. Please list all existing health care providers (i.e.-Hospitals m nursing homes, home care organization, etc.) management care organizations, alliances and/or networks with which the applicant currently has or plan to have contractual and/or working relationships.

These will be provided under separate cover.

Page Sixteen April 26, 2013

19. Section C, Orderly Development, Item 2.

a. Please indicate the reason why the applicant and Molecular Imaging Alliance did not split the original service area for the two existing PET units the applicant proposes to acquire that are currently located in Gray, Tennessee?

The applicant and Molecular Imaging Alliance have overlapping service areas now. However, although WCS and Molecular's patients come from overlapping service areas, they will come through completely different referral sources. Both providers should continue to meet the needs of their referral sources. It is not up to the applicant to direct referral volumes. An agreement to divide the market may not even be lawful.

At any rate, WCS's projected procedures will fully utilize its own unit with patients who currently are not obtaining cardiac PET scans from Gray--regardless of where they live within the service area. So WCS feels that its unit at Kingsport will not reduce the utilization projections of the unit at Johnson City.

b. Is the applicant and Molecular Imaging Alliance planning to sign a non-compete contract in the proposed service area?

No, they are not.

Additional Information From Applicant

John Wellow

Attached are copies of the CV's and documentation of certifications to read nuclear imaging PET procedures, for the physicians who will interpret the cardiac PET studies.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please FAX or telephone me so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn

SUPPLEMENTAL-#1

April 26, 2013 1:15 pm

Single-photon emission computed tomography

From Wikipedia, the free encyclopedia

Single-photon emission computed tomography (SPECT, or less commonly, SPET) is a nuclear medicine tomographic^[1] imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera. However, it is able to provide true 3D information. This information is typically presented as cross-sectional slices through the patient, but can be freely reformatted or manipulated as required.

The basic technique requires delivery of a gamma-emitting radioisotope (called radionuclide) into the patient, normally through injection into the bloodstream. On occasion, the radioisotope is a simple soluble dissolved ion, such as a radioisotope of gallium(III), which happens to also have chemical properties that allow it to be concentrated in ways of medical interest for disease detection. However, most of the time in SPECT, a marker radioisotope, which is of interest only for its radioactive properties, has been attached to a specific ligand to create a radioligand, which is of interest for its chemical binding properties to certain types of tissues. This marriage allows the combination of ligand and radioisotope (the radiopharmaceutical) to be carried and bound to a place of interest in the body, which then (due to the gamma-emission of the isotope) allows the ligand concentration to be seen by a gamma-camera.

Single-photon emission computed tomography

Intervention



A SPECT slice of the distribution of technetium exametazime within a patient's brain.

ICD-9- 92.0 (http://icd9cm.chrisendres.com/index.php?

CM srchtype=procs&srchtext=92.0&Submit=Search&action=search)-92.1 (http://icd9cm.chrisendres.com/index.php?

srchtype=procs&srchtext=92.1&Submit=Search&action=search)

MeSH D015899

3-72 (http://ops.icd-code.de/ops/code/3-72.html)

OPS-301 code:

Contents

- 1 Principles
- 2 Application
 - 2.1 Myocardial perfusion imaging
 - 2,2 Functional brain imaging
- 3 Reconstruction
- 4 Typical SPECT acquisition protocols
- 5 SPECT/CT
- 6 See also
- 7 References
- 8 Further reading
- 9 External links

Principles

In the same way that a plain X-ray is a 2-dimensional (2-D) view of a 3-dimensional structure, the image obtained by a gamma camera is a 2-D view of 3-D distribution of a radionuclide.

SPECT imaging is performed by using a gamma camera to acquire multiple 2-D images (also called projections), from multiple angles. A computer is then used to apply a tomographic reconstruction algorithm to the multiple projections, yielding a 3-D dataset. This dataset may then be manipulated to show thin slices along any chosen axis of the body, similar to those obtained from other tomographic techniques, such as MRI, CT, and PET.

SPECT is similar to PET in its use of radioactive tracer material and detection of gamma rays. In contrast with PET, however, the tracer used in SPECT emits gamma radiation that is measured directly,



SPECT Siemens brand. It consists of

whereas PET tracer emits positrons that annihilate with electrons up to a few millimeters away, causing two gamma photons to be emitted in opposite directions. A PET scanner detects these emissions "coincident" in time, which provides more radiation event localization information and, thus, higher resolution images than SPECT (which has about 1 cm resolution). SPECT scans, however, are significantly less expensive than PET scans, in part because they are able to use longerlived more easily-obtained radioisotopes than PET.

Because SPECT acquisition is very similar to planar gamma camera imaging, the same radiopharmaceuticals may be used. If a patient is examined in another type of nuclear medicine scan but the images are non-diagnostic, it may be possible to proceed straight to SPECT by moving the patient to a SPECT instrument, or even by simply reconfiguring the camera for SPECT image acquisition while the patient remains on the table.



SPECT machine performing a total body bone scan. The patient lies on a table that slides through the machine, while a pair of gamma cameras rotate around her.

To acquire SPECT images, the gamma camera is rotated around the patient. Projections are acquired at defined points during the rotation, typically every 3-6 degrees. In most cases, a full 360-degree rotation is used to obtain an optimal reconstruction. The time taken to obtain each projection is also variable, but 15–20 seconds is typical. This gives a total scan time of 15–20 minutes.

Multi-headed gamma cameras can provide accelerated acquisition. For example, a dual-headed camera can be used with heads spaced 180 degrees apart, allowing 2 projections to be acquired simultaneously, with each head requiring 180 degrees of rotation. Triple-head cameras with 120-degree spacing are also used.

Cardiac gated acquisitions are possible with SPECT, just as with planar imaging techniques such as MUGA. Triggered by Electrocardiogram (EKG) to obtain differential information about the heart in various parts of its cycle, gated myocardial SPECT can be used to obtain quantitative information about myocardial perfusion, thickness, and contractility of the myocardium during various parts of the cardiac cycle, and also to allow calculation of left ventricular ejection fraction, stroke volume, and cardiac output.

Application

SPECT can be used to complement any gamma imaging study, where a true 3D representation can be helpful, e.g., tumor imaging, infection (leukocyte) imaging, thyroid imaging or bone scintigraphy.

Because SPECT permits accurate localisation in 3D space, it can be used to provide information about localised function in internal organs, such as functional cardiac or brain imaging.

Myocardial perfusion imaging

Main article: Myocardial perfusion imaging

Myocardial perfusion imaging (MPI) is a form of functional cardiac imaging, used for the diagnosis of ischemic heart disease. The underlying principle is that under conditions of stress, diseased myocardium receives less blood flow than normal myocardium. MPI is one of several types of cardiac stress test.

A cardiac specific radiopharmaceutical is administered, e.g., 99mTc-tetrofosmin (Myoview, GE healthcare), 99mTc-sestamibi (Cardiolite, Bristol-Myers Squibb). Following this, the heart rate is raised to induce myocardial stress, either by exercise or pharmacologically with adenosine, dobutamine, or dipyridamole (aminophylline can be used to reverse the effects of dipyridamole).

SPECT imaging performed after stress reveals the distribution of the radiopharmaceutical, and therefore the relative blood flow to the different regions of the myocardium. Diagnosis is made by comparing stress images to a further set of images obtained at rest. As the radionuclide redistributes slowly, it is not usually possible to perform both sets of images on the same day, hence a second attendance is required 1-7 days later (although, with a Tl-201 myocardial perfusion study with dipyridamole, rest images can be acquired as little as two hours post-stress). However, if stress imaging is normal, it is unnecessary to perform rest imaging, as it too will be normal; thus, stress imaging is normally performed first.

MPI has been demonstrated to have an overall accuracy of about 83% (sensitivity: 85%; specificity: 72%), [2] and is comparable with (or better than) other non-invasive tests for ischemic heart disease.

SUPPLEMENTAL- # 1 April 26, 2013

pril 26, 2013 1:15 pm

Functional brain imaging

Main article: Neuroimaging

Usually, the gamma-emitting tracer used in functional brain imaging is ^{99m}Tc-HMPAO (hexamethylpropylene amine oxime). ^{99m}Tc is a metastable nuclear isomer that emits gamma rays that can be detected by a gamma camera. Attaching it to HMPAO allows ^{99m}Tc to be taken up by brain tissue in a manner proportional to brain blood flow, in turn allowing cerebral blood flow to be assessed with the nuclear gamma camera.

Because blood flow in the brain is tightly coupled to local brain metabolism and energy use, the ^{99m}Tc-HMPAO tracer (as well as the similar ^{99m}Tc-EC tracer) is used to assess brain metabolism regionally, in an attempt to diagnose and differentiate the different causal pathologies of dementia. Meta-analysis of many reported studies suggests that SPECT with this tracer is about 74% sensitive at diagnosing Alzheimer's disease vs. 81% sensitivity for clinical exam (cognitive testing, etc.). More recent studies have shown the accuracy of SPECT in Alzheimer's diagnosis may be as high as 88%.^[3] In meta analysis, SPECT was superior to clinical exam and clinical criteria (91% vs. 70%) in being able to differentiate Alzheimer's disease from vascular dementias.^[4] This latter ability relates to SPECT's imaging of local metabolism of the brain, in which the patchy loss of cortical metabolism seen in multiple strokes differs clearly from the more even or "smooth" loss of non-occipital cortical brain function typical of Alzheimer's disease.

^{99m}Tc-HMPAO SPECT scanning competes with fludeoxyglucose (FDG) PET scanning of the brain, which works to assess regional brain glucose metabolism, to provide very similar information about local brain damage from many processes. SPECT is more widely available, because the radioisotope used is longer-lasting and far less expensive in SPECT, and the gamma scanning equipment is less expensive as well. While ^{99m}Tc is extracted from relatively simple technetium-99m generators, which are delivered to hospitals and scanning centers weekly to supply fresh radioisotope, FDG PET relies on FDG, which is made in an expensive medical cyclotron and "hot-lab" (automated chemistry lab for radiopharmaceutical manufacture), and then delivered immediately to scanning sites because of the natural short 110-minute half-life of Fluorine-18.

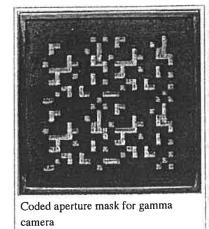
Reconstruction

Reconstructed images typically have resolutions of 64×64 or 128×128 pixels, with the pixel sizes ranging from 3–6 mm. The number of projections acquired is chosen to be approximately equal to the width of the resulting images. In general, the resulting reconstructed images will be of lower resolution, have increased noise than planar images, and be susceptible to artifacts.

Scanning is time consuming, and it is essential that there is no patient movement during the scan time. Movement can cause significant degradation of the reconstructed images, although movement compensation reconstruction techniques can help with this. A highly uneven distribution of radiopharmaceutical also has the potential to cause artifacts. A very intense area of activity (e.g., the bladder) can cause extensive streaking of the images and obscure neighboring areas of activity. (This is a limitation of the filtered back projection reconstruction algorithm. Iterative reconstruction is an alternative algorithm that is growing in importance, as it is less sensitive to artifacts and can also correct for attenuation and depth dependent blurring).

Attenuation of the gamma rays within the patient can lead to significant underestimation of activity in deep tissues, compared to superficial tissues. Approximate correction is possible, based on relative

deep tissues, compared to superficial tissues. Approximate correction is possible, based on relative position of the activity. However, optimal correction is obtained with measured attenuation values. Modern SPECT equipment is available with an integrated X-ray CT scanner. As X-ray CT images are an attenuation map of the tissues, this data can be incorporated into the SPECT reconstruction to correct for attenuation. It also provides a precisely registered CT image, which can provide additional anatomical information.



Typical SPECT acquisition protocols

Study	Radioisotope	Emission energy (keV)	Half- life	Radiopharmaceutical	Activity (MBq)	Rotation (degrees)	Projections	Image resolution	Time per projection (s)
	technetium-		6	Phosphonates /					

Bone scan	one scan 99m 140 hours Bisphosphonates 800 360				360	UPPLE	MENT/	AL-#1 26, 2013	
Myocardial perfusion scan	technetium- 99m	140	6 hours	tetrofosmin; Sestamibi	700	180	60	64 x 64	1515 pm
Sestamibi parathyroid scan	technetium- 99m	140	6 hours	Sestamibi					
Brain scan	technetium- 99m	140	6 hours	HMPAO; ECD	555- 1110	360	64	128 x 128	30
Neuroendocrine or neurological tumor scan	iodine-123 or iodine-131	159	hours or 8 days	MIBG	400	360	60	64 x 64	30
White cell scan	indium-111 & technetium- 99m	171 & 245	67 hours	in vitro labelled leucocytes	18	360	60	64 x 64	30

SPECT/CT

In some cases a SPECT gamma scanner may be built to operate with a conventional CT scanner, with coregistration of images. As in PET/CT, this allows location of tumors or tissues which may be seen on SPECT scintigraphy, but are difficult to precisely locate with regard to other anatomical structures. Such scans are most useful for tissues outside the brain, where location of tissues may be far more variable. For example, SPECT/CT may be used in sestamibi parathyroid scan applications, where the technique is useful in locating ectopic parahyroid ademomas which may not be in their usual locations in the thyroid gland.^[5]

See also

- Gamma camera
- Neuroimaging
- Functional neuroimaging
- Magnetic resonance imaging
- Positron emission tomography
- ISAS (Ictal-Interictal SPECT Analysis by SPM)

References

- SPECT (http://www.nlm.nih.gov/cgi/mesh/2011/MB_cgi?mode=&term=SPECT) at the US National Library of Medicine Medical Subject Headings (MeSH)
- 2. A Elhendy, A; Bax, JJ; Poldermans, D (2002). "Dobutamine stress myocardial perfusion imaging in coronary artery disease.". Journal of Nuclear Medicine 43 (12): 1634-46. PMID 12468513 (//www.ncbi.nlm.nih.gov/pubmed/12468513).
- A Bonte FJ, Harris TS, Hynan LS, Bigio EH, White CL (2006). "Tc-99m HMPAO SPECT in the differential diagnosis of the dementias with histopathologic confirmation". Clin Nucl Med 31 (7): 376–8. doi:10.1097/01.rlu.0000222736.81365.63 (http://dx.doi.org/10.1097%2F01.rlu.0000222736.81365.63). PMID 16785801 (//www.ncbi.nlm.nih.gov/pubmed/16785801).
- A Dougall NJ, Bruggink S, Ebmeier KP (2004). "Systematic review of the diagnostic accuracy of 99mTc-HMPAO-SPECT in dementia". Am J Geriatr Psychiatry 12 (6): 554

 —70. doi:10.1176/appi.ajgp.12.6.554 (http://dx.doi.org/10.1176%2Fappi.ajgp.12.6.554). PMID 15545324 (//www.ncbi.nlm.nih.gov/pubmed/15545324).
- 5. ^[1] (http://www.ncbi.nlm.nih.gov/pubmed/18997051) PET/CT sestamibi vs. other modalities for parathyroid imaging

Further reading

- Herman, Gabor T. (2009). Fundamentals of Computerized Tomography: Image Reconstruction from Projections (2nd ed.). Springer. ISBN 978-1-85233-617-2...
- Elhendy et al., Dobutamine Stress Myocardial Perfusion Imaging in Coronary Artery Disease, J Nucl Med 2002 43: 1634–1646 (http://jnm.snmjournals.org/cgi/content/abstract/43/12/1634)

AFFIDAVIT

2013 APR 26 PM 1: 20

STATE OF TENNESSEE **COUNTY OF DAVIDSON**

NAME OF FACILITY:
WELLMONT CARDIOLOGY SERVICES
I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful
agent of the applicant named in this Certificate of Need application or the lawful agent
thereof, that I have reviewed all of the supplemental information submitted herewith,
and that it is true, accurate, and complete to the best of my knowledge.

Sworn to and subscribed before me, a Notary Public, this the 2 day of 400, 2013, witness my hand at office in the County of PAVIOSA ___, State of Tennessee.

Signature/Title

- , 2017. My commission expires

HF-0043

Revised 7/02

COPY-ADDITIONAL Info

SUPPLEMENTAL-1

Wellmont Cardiology Services, Inc.

CN1304-013

DSG Development Support Group

April 29, 2013 4:20 pm

2013 APR 29 PM 4 19

April 29, 2013

Phillip M. Earhart, Health Planner III Tennessee Health Services and Development Agency 161 Rosa L. Parks Boulevard Nashville, Tennessee 37203

RE:

CON Application CN1304-013 Wellmont Cardiology Services, Inc.

Dear Mr. Earhart:

This letter provides additional responses to several questions that could not be fully addressed in the applicant's April 26 responses to your First Supplemental Questions. The items below are numbered to correspond to those questions. They are provided in triplicate, with affidavit.

8. Section C, Need, Item 1. (Project-Specific Criteria: PET Scanners)
The proposed project is changing ownership, proposed service area and location. Please address the revised and Updated standards for Positron Emission Tomography (PET) services found in the State Health Plan.

Please see the new responses attached after this letter, to replace originally submitted page 20 of the application. The revised pages are 20a-R through 20n-R. This allows them to be inserted into the application where they belong, for future reference.

- 9. Section C, Need, Item 1. (Project-Specific Criteria: Outpatient Diagnostic Centers)
 - a. Item #1-Please address the need for outpatient diagnostic services by county projecting four years into the future using available population figures.

Please see the new responses attached after this letter, revising originally submitted pages 21-23 of the application. The revised pages are 21R, 22R, and 23a-R through 23c-R. This allows them to be inserted into the application where they belong, for future reference.

April 29, 2013 4:20 pm

Page Two April 29, 2013

2013 APR 29 PM 4 19

11. Section C, Need, Item 5

c. The applicant has provided table eight that displays utilization for Molecular Imaging Alliance Cardiac PET only. Please revise and include all PET units in the proposed service area and indicate if cardiac PET services are attached to each unit listed, and if the unit is fixed or mobile.

Attached following this page is an HSDA Registry report with the requested information for 2009-2012. It is revised page 31b-R, to go after the original page 31 that provided information only on the applicant.

The new page is HSDA data, whereas the original page 31 shows JAR data and the applicant's internal data for CY2012. The applicant actually provided slightly more procedures than the Registry shows, because the applicant did not include non-Tennessee residents in its submittal to HSDA. That insignificant discrepancy will be corrected under separate cover.

The applicant has no way to ascertain (a) whether the PET units other than Wellmont's unit are equipped with the special hardware and software options needed to perform cardiac PET studies, or (b) the number of cardiac studies such PET's can perform given their high utilization for oncology studies. Wellmont's mobile PET unit allows no more than 300 cardiac patient studies per year. There is no publicly available information on such limits that may be in place at other PET units.

13. Section C. Economic Feasibility Item 1 (Project Cost Chart)

The applicant has listed \$2,410 as the CON filing fee on the Project Cost Chart. Please revise with the correct CON filing fee and resubmit a revised Project Cost Chart.

Please excuse the misunderstanding that this should reflect the minimum filing fee of \$3,000.00, which was in fact submitted with the application. Attached is revised page 35R, the Project Review Chart.

April 29, 2013 4:20 pm

Page Three April 29, 2013

15. Section C, Economic Feasibility, Item 4.

a. Please itemize "D.3 Supplies" located on the Projected Data Chart in the amounts of \$588,000 and \$605,640 for the Years 2014 and 2015, respectively.

The applicant calculated supplies for Year One, and then increased the total for Year Two by 3% to allow for potential price increases.

	Year 1	Year 2
Patients	1,500	1,500
General supplies @ \$12 per patient	\$ 18,000	\$ 18,540
N-13 @ \$320 (2 doses) per patient	\$480,000	\$494,400
Lexiscan (stress agent) @ \$60 per patient	\$ 90,000	\$ 92,700
Total	\$588,000	\$605,640 (+3%)

18. Section C, Orderly Development, Item 1.

The applicant states there are no shortage of working relationships between the applicant and any level of healthcare provider that might be needed. Please list all existing health care providers (i.e.-Hospitals m nursing homes, home care organization, etc.) management care organizations, alliances and/or networks with which the applicant currently has or plan to have contractual and/or working relationships.

The applicant is contracted with all three area TennCare MCO's and the Virginia program, as listed on page 4 of the application: BlueCare, United Community Healthcare Plan, TennCare Select, and Virginia Medicaid.

As a wholly-owned medical group practice in the Wellmont Health System, WCS has strong relationships with Wellmont Holston Valley Medical Center (HVMC), to whose patients WCS is the largest provider of cardiology care. An emergency transfer agreement if required by law or the HSDA will be executed with that facility. The Medical Director for the project will have staff privileges at HVMC.

WCS physicians direct the post-acute care plans for their cardiology patients who are discharged from HVMC (and other Wellmont hospitals). They actively work with large numbers of area nursing homes, home health agencies, and related post-acute providers. Attached after this letter are lists of many such agencies.

And, as explained in Section C(III)6 of the application, WCS physicians support the Family Medicine and Internal Medicine training program operated by East Tennessee State University. WCS also supports the rural-based, Family Medicine residency program operated by Wellmont Health System in formal collaboration with the Debusk College of Osteopathic Medicine. WCS has numerous training and educational

April 29, 2013 4:20 pm

Page Four April 29, 2013

affiliations with academic institutions throughout the southeastern U.S., which supports nursing training, imaging technologists training and the training of other allied health professionals. WCS operates a division called "Cardiovascular University" which offers hands-on training programs in Kingsport to cardiologists, vascular surgeons, nurse practitioners, physician assistants and other healthcare professionals.

Additional Information From Applicant

ohn Wellow

The time required for a SPECT scan for a single patient requires patient availability for a minimum of 3 hours. It consists of imaging of the heart at rest, and then under stress. The "at rest" phase requires an injection and an hour wait time for medication uptake by the body. Then the scan time is just under 30 minutes. The "stress" phase is a repeat of that. At a low-volume provider, those phases can follow one another immediately, so the patient is on-site for 3 to 4 hours. At a high-volume provider like Wellmont, the rest phase tests for all the day's patients are typically performed in the morning, and their stress phase tests are performed in the afternoon of the same day. In those situations, patients are on-site longer than 4 hours.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please FAX or telephone me so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn Consultant

SUPPLEMENTAL April 29, 2013 4:20 pm

AFFIDAVIT

2013 APR 29 PM 4 20

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:
Will mont Cardi 6 lexy Suras OTX / PET
I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful
agent of the applicant named in this Certificate of Need application or the lawful agent
thereof, that I have reviewed all of the supplemental information submitted herewith,
and that it is true, accurate, and complete to the best of my knowledge.
Signature/Title
Sworn to and subscribed before me, a Notary Public, this the 29 day of APRIC, 2013
witness my hand at office in the County of PALOSA, State of Tennessee.
NOTARY PUBLIC
My commission expires
WILLE ANY B
HF-0043
Revised 7/02

Copy

Extra additional information for Supplemental #1

Wellmont Cardiology Services

CN1304-013

DSG Development Support Group

April 30, 2013 3:47 5m

2013 APR 30 PM 3 41

April 30, 2013

Phillip M. Earhart, Health Planner III Tennessee Health Services and Development Agency 161 Rosa L. Parks Boulevard Nashville, Tennessee 37203

RE: CON Application CN1304-013

Wellmont Cardiology Services, Inc.

Dear Mr. Earhart:

This letter is to provide one additional response to your recent letter requesting supplemental information on the subject project.

8. Section C, Need, Item 1. (Project-Specific Criteria: PET Scanners)
The proposed project is changing ownership, proposed service area and location. Please address the revised and Updated standards for Positron Emission Tomography (PET) services found in the State Health Plan.

In the applicant's April 29 response to the PET criteria, response to criterion 6d (medical necessity) directed the reviewer's attention to an attached protocol, which was labeled "Critical Results Policy--Cardiac PET Protocol."

We noticed that the submitted draft protocol was not the correct one; it did not address criterion 6d. I am attaching a Wellmont draft protocol specific to ensuring the medical necessity of PET procedures, to address PET criterion 6d.

Sincerely, Oolin Wellborn

John Wellborn

Consultant

3:47 5m

AFFIDAVIT 2013 APR 30 PM 3 41

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

WELLMONT CARDIOLOGY SERVICES - KINGSPORT

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

Signature/Title

Sworn to and subscribed before me, a Notary witness my hand at office in the County of		36 day of ARLL, 2013 State of Tennessee.
	20	
	NOTARY P	UBLIC MINIMINE
My commission expires	-,2017.	TIFFAN DO O
HF-0043		DSO SON AND SON
Revised 7/02		NTY WHITE
		, , , so 13

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Times-News, which is general circulation in Sullivan County, Tennessee, on or before April 10	3a newspaper of
general circulation in Sullivan County, Tennessee, on or before April 10	, 2013, for one
day.	

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Wellmont Cardiology Services, Inc. (a not-for-profit corporation and physician group practice), wholly owned and operated by Wellmont Health Systems dba Wellmont CVA Heart Institute (a not-for-profit corporation), intends to file an application for a Certificate of Need to (a) acquire an existing cardiac PET system now serving patients in Gray, Tennessee, and to (b) relocate that PET system to, and initiate cardiac PET services at, the Wellmont CVA Heart Institute building at 2050 Meadowview Parkway, Kingsport, TN 37660, and to (c) establish an Outpatient Diagnostic Center ("ODC") to offer that PET service at that site, if required by the Tennessee Department of Health. The project's capital cost is estimated at \$1,100,000.

If required, the applicant will seek licensure of this cardiac PET facility as an Outpatient Diagnostic Center, from the Board for Licensing Health Care Facilities, Tennessee Department of Health. The project does not contain any other type of major medical equipment, or initiate or discontinue any other significant health service. It will not affect any licensed bed complements.

The anticipated date of filing the application is on or before April 15, 2013. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 203, Nashville, TN 37215; (615) 665-2022.

John Livelloom 4-8-13 jwdsg@comcast.net
(Signature) (Date) (E-mail Address)

CERTIFICATE OF NEED REVIEWED BY THE DEPARTMENT OF HEALTH DIVISION OF HEALTH STATISTICS

615-741-1954

DATE: July 1, 2013

APPLICANT: Wellmont Cardiology Services

2050 Meadowview Parkway Gray, Tennessee 37615

CONTACT PERSON: John L. Wellborn

Development Support Group 4219 Hillsboro Road, Suite 203 Nashville, Tennessee 37215

COST: \$1,074,000

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's Health: Guidelines for Growth, 2011 Edition*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Wellmont Cardiology Services, (WCS) located in Kingsport (Sullivan County), Tennessee, seeks Certificate of Need (CON) approval to (a) acquire an existing cardiac positron emission tomography (PET) system now serving patients in Gray, Tennessee, (b) initiate PET services at Wellmont CVA Heart Institute building at 2050 Meadowview Parkway, Kingsport, Tennessee, and (c) establish an Outpatient Diagnostic Center (ODC) to offer PET service at the aforementioned site. The PET system being acquired is a Siemmens 2000 LS-EXCAT system.

WCS proposes to purchase an existing cardiac PET scanning system now operating at Molecular Imaging Alliance ODC in Gray, Tennessee. Molecular Imaging has filed a CON application (CN1304-014) to relocate to Johnson City where it will need only one PET system. These two CON applications for service relocations have been filled as companion applications. The two related projects will not increase the number of PET units operating in the service area. Their combined service areas in the future will be the same as today, the counties of upper East Tennessee plus nearby counties in Southwest Virginia. The applicant does not intend to create a new licensed facility, but rather to move an existing cardiac PET unit, now at a remote location, into the main office of the practice in Kingsport where it will be utilized more frequently.

The project involves the renovation of 2,080 square feet at a cost of \$520,000, or \$250 per square foot. The cost to renovate is higher than the range for ODC on the HSDA Registry for 2008-20010, but within the third quartile range for projects in 2012.

WCS, Inc. is a not-for-profit physician practice corporation whose sole member/owner is Wellmont Health System, a not-for-profit healthcare system based in the Tri-Cities area of Upper East Tennessee and Southwest Virginia. The system operates several hospitals in the region, including Holston Valley Medical Center in Kingsport. It is one of the State's largest tertiary healthcare networks. Attachment A.4 contains details and information about the Tennessee facilities owned by this facility's parent organization.

The estimated total project cost is \$1,074,000 and will be funded through cash reserves of Wellmont Health System as documented in Attachment C, Economic Feasibility-2.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's Health: Guidelines for Growth, 2000 Edition.*

NEED:

The applicant's service area includes Carter, Cocke, Greene, Hamblen, Hancock, Hawkins, Johnson, Sullivan, Unicoi, and Washington in Tennessee, and Washington, Wise, Scott, Russell, Lee, and Smyth counties in Virginia.

Tennessee Service Area Total Population Projections for 2013 and 2017

County	2013 Population	2017 Population	% Increase/ (Decrease)	
Carter	60,119	60,700	1.0%	
Cocke	37,001	38,848	2.3%	
Greene	68,390	69,636	1.8%	
Hamblen	63,947	65,455	2.4%	
Hancock	6,832	6,990	0.7%	
Hawkins	60,131	61,865	2.9%	
Johnson	18,881	19,254	2.0%	
Sullivan	154,387	154,946	0.4%	
Unicoi	17,903	17,982	0.4%	
Washington	120,136	123,276	2.6%	
Totals	607,727	618,952	1.8%	

Source: Tennessee Population Projections 2000-2020, February 2008 Revision, Tennessee Department of Health, Division of Health Statistics

The following chart illustrates the service area utilization.

Service Area PET Utilization, 2012

Service Area PET Offitzation, 2012						
Facility	County	Fixed Units	Procedures	Mobile Units	Procedures	
Laughlin Memorial Hospital	Greene	0	0	1 unit 1 day	351	
Morristown- Hamblen Hospital	Hamblen	0	0	1 unit 2 days	405	
Bristol Regional Medical Center	Sullivan	0	0	1 unit 3 days	1,677	
Holston Valley Medical Center	Sullivan	0	0	1 unit 3 days	460	
Indian Path Medical Center	Sullivan	0	0	1 unit 1 day	143	
Johnson City Medical Center	Washington	1	1,234	0	0	
Molecular Imaging (LifeScan)	Washington	2	623	0	0	
Total		3	1.857	6	6,236	

Source: Health Services and Development Agency Equipment Registry

WCS is a physician based practice that includes 47 cardiologists, cardiovascular, vascular, and cardiothoracic surgeons, and 23 nurse practitioners and physician assistants. In the previous year, WCS had 45,000 active patients. Their main office is located in the Wellmont building known as "The Heart Center" and shares the building with the Holston Valley Medical Center, which operates several diagnostic services there.

The applicant wants to acquire the existing cardiac PET system from Molecular Imaging and relocate it 10.6 miles west to Kingsport, into their practice offices to provide diagnostic service to a larger volume of their patients then have access to the current location in Gray, Tennessee. Molecular Imaging has two systems but will keep only one. This provides the applicant to acquire an economically priced and dependable Siemens Cardiac PET system to improve the diagnostic information for patients who would benefit from it. Acquiring this unit will not reduce the utilization of the only provider in the region, Molecular Imaging, in Gray. The ODC and WCS are simultaneously filing CON applications to relocate one cardiac PET system each, to Johnson City and Kingsport, respectively. This will not only make the systems more accessible to the majority of patients and referring physicians, but increase each systems use.

WCS estimates 1,500 patients per year could benefit from having diagnostic tests performed on the cardiac PET system. The current location of the PET is in the small town of Gray that is not accessible to many of the practice's patients and WCS's cardiologists must travel with them to supervise the test. Relocating the PET in-house will increase the system's utilization as well as improving diagnosis and eliminating many interventional procedures.

The project does not duplicate existing technology and does not serve counties not already being served. The CON was previously approved for Molecular Imaging. This application, as well as Molecular Imaging's CON, relocates both systems and reassigns ownership of one system to WCS.

TENNCARE/MEDICARE ACCESS:

The applicant is an existing physician practice entity that already is certified for Medicare and TennCare. WCS contracts with BlueCare, United Community Healthcare Plan, TennCare Select, and Virginia Medicaid.

The payor mix for the proposed new nuclear medicine service is \$3,795,995 or 68.8% Medicare and \$187,593 or 3.4% TennCare.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment have reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine they are mathematically accurate and the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located in Supplemental 1, Additional Information. The projects total estimated project cost is \$1,074,000.

Historical Data Chart: There is no Historical Data Chart due to this being a proposed new project.

Projected Data Chart: The Projected Data Chart is located on page 39 of the application. The applicant projects 1,500 procedures in year one and two with a net operating income of \$242,593 and \$220,693 each year, respectively.

The applicant's years one and two average gross charge is estimated to be \$3,678, with and average deduction of \$2,538, resulting in an average net charge of \$1,140. The applicant compares their net charge with Molecular Imaging Alliance, ODC \$1,764 and Molecular Imaging Alliance, Johnson City \$1,710.

If WCS did not acquire this equipment and relocate to Kingsport where it can be medically supervised and highly utilized, it might lose what limited access it now has to cardiac PET imaging. The ODC in Gray is the region's only source of service. It intends to move to Johnson City, doubling the distance between Kingsport and the service. The ODC has also told its equipment

leasing company that it will lease only one PET unit at the new location; and there is a possibility that it will be so busy in a few years that WCS patients will have even less access to it than it currently has, even if it's patients are willing to drive the extra distance to Johnson City.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

WCS is under the organizational umbrella of the Wellmont Health System in Kingsport, with one of the State's largest tertiary care hospitals only minutes away. There is no shortage of working relationships between the applicant and any level of healthcare provider. The applicant provides a listing of these providers in Supplemental 1, Additional Information. No transfer agreement will be needed because the service will be within the medical practice with numerous physicians and nurses available as first responders to any emergency needs of patients being scanned. If an emergency agreement is necessary, an emergency transfer agreement will be sought with Holston Valley Medical Center in Kingsport.

This is not a duplicative or competitive project. It is only a change in location and ownership of a CON approved cardiac PET system that has been serving the same area counties that WCS serves. The cardiac PET system will greatly increase as a result of moving north from Gray. The increased utilization will come from WCS's own internal procedure conversions and follow up tests, not from volumes of other PET providers.

The projected year one and two staffing includes 1.0 FTE registered nurse, 1.0 FTE nuclear medicine technologist, and 1.0 FTE clerical position.

Wellmont Health System and WCS support a wide variety of medical related training and educational programs. WCS physicians support the Family Medicine and Internal Medicine training program operated by East Tennessee State University. WCS also supports the rural-based, Family Medicine residency program operated by Wellmont Health System in formal collaboration with the Debusk College of Osteopathic Medicine. WCS operates a division called "Cardiovascular University" which offers hands-on training programs in Kingsport to cardiologists, vascular surgeons, nurse practitioners, physician assistants, and other healthcare professionals.

The applicant will be licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities, Tennessee Department of Environment and Conservation, and will seek accreditation from the Intersocietal Accreditation Commission for Nuclear Cardiology, Nuclear Medicine, and Positron Emission Tomography.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's Health: Guidelines for Growth, 2000 Edition.*

OUTPATIENT DIAGNOSTIC CENTERS

1. The need for outpatient diagnostic services shall be determined on a county by county basis (with data presented for contiguous counties for comparative purposes) and should be projected four years into the future using available population figures.

The county where the project is located is Sullivan County, with contiguous counties including Hawkins, Washington, Carter, and Johnson counties. These are only half of the Tennessee primary service area counties to be served by this project, and none of the Virginia counties. The applicant believes the criterion's methodology appears to not be useful or logical for evaluating need for this project. The need basis for this project is discussed in several sections of the application, especially B.II.C. The need basis is the actual number of patients being seen by the applicant's physicians, and patients currently in need of the utilization projected for this project.

The applicant provides a table illustrating the five counties current population projected to 2013. A second table shows the identifiable actual plus potential cardiac PET scasn needed by residents of the five counties, according to Joint Annual Reports of the area's only dedicated cardiac PET provider, with projections from WCS records.

2. Approval of additional outpatient diagnostic services will be made only when it is demonstrated that existing services in the applicant's geographical service area are not adequate and/or there are special circumstances that require additional services.

The applicant states the criterion is met because physical accessibility to this service in Gray is not adequate currently for WCS cardiologists, and because the service provider is planning to relocate almost twice as far away, making access completely unfeasible for Kingsport cardiologists. The only know option for this service in Kingsport—use of the Welmont Holston Valley Medical Center mobile PET unit. The unit currently restricts the number of cardiac PET scans to no more than 300 per year. This is less than 17% of the total number of WCS patients that would need to schedule this test.

- 3. Any special needs and circumstances:
 - a. The needs of both medical and outpatient diagnostic facilities and services must be analyzed.

The need addressed by this application is for certain large-body-mass patients in WCS offices (currently 1,500 per year) to have access to a cardiac PET scan in place of, or to supplement, the SPECT tests that are their only other option in Kingsport. They cannot do so now, because the regions only cardiac PET in Gray is too far away to allow WCS physicians to routinely go there to supervise their patients' tests. Now that the Gray facility is moving almost twice as far away from Kingsport, and willing to take with it only one of the two PET units it operates in Gray, it is logical for WCS to acquire the other existing unit and move it to Kingsport to eliminate accessibility issues for a large WCS patient population.

There are no other medical offices, or ODC's that will be affected by the project. But the project would clearly improve these particular patients' healthcare and the total costs of their care.

b. Other special needs and circumstances, which might be pertinent, must be analyzed.

No special needs and circumstances have been identified.

- c. The applicant must provide evidence that the proposed diagnostic outpatient services will meet the needs of the potential clientele to be served.
 - 1. The applicant must demonstrate how emergencies within the outpatient diagnostic facility will be managed in conformity with accepted medical practice.

The proposed ODC will be located in The Heart Center office building, within a group practice of cardiac care specialists who have admitting privileges at nearby Holston Valley Medical Center. No transfer agreement will be needed because the service will be within the medical practice with numerous physicians and nurses available as first responders to any emergency needs of patients being scanned. If an emergency agreement is necessary, an emergency transfer agreement will be sought with Holston Valley Medical Center in Kingsport.

The applicant must establish protocols that will assure that all clinical procedures
performed are medically necessary and will not unnecessarily duplicate other
services.

The applicant attached draft protocols in criterion 6d of the PET CON review standards and criteria.

PET Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter.

Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1,600 procedures per year if the unit is operated more than five (5) days per week.

The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

The applicant expects to perform 1,600 procedures in the third year of service.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population.

Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

Not applicable. The need basis for this project is discussed in several sections of the application, especially B.II.C. The need basis is the actual number of patients being seen by the applicant's physicians, and patients currently in need of the utilization projected for this project.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

The Virginia service area includes Wise. Scott, Russell, Lee, and Smythe counties.. Johnson Memorial Medical Center has a mobile PET but utilization is not known.

There is no known shared service that is accessible to WCS physicians and no lower cost technology.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

Not applicable.

A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures /day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The applicant expects to perform 1,600 procedures in the third year of service.

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

Not applicable. The applicant is not requesting an additional unit.

- 6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

Documentation was submitted by the applicant.

b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Compliance to the applicable standards and regulations is assured by the architect's letter.

c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

The applicant provided draft protocols for emergency response.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

Protocols to assure medical appropriateness and medical necessity are included in the Attachments.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

The Medical Director has not been identified. Additionally, the applicant believes that standards should be assumed to include such specialties because that is an industry standard.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

The practice will seek a transfer agreement with Holston Valley Medical Center.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant agrees to comply.

- 8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:
- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - WCS's service are covers large numbers of medically underserved areas in Tennessee and southwest Virginia.
- Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

The applicant is not claiming this special circumstance at this time.

c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

WCS is wholly owned by Wellmont Health System, whose tertiary referral hospital in Kingsport, Holston Valley Medical Center, is a practice site for WCS physicians. The facility is designated by TennCare as a safety net hospital. It is also designated as a Comprehensive Cancer Center Diagnosis and Treatment Program location.

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant contracts with all TennCare MCO's and with Medicare.

Letters of Support

Wellmont CVA Heart Institute

CN1304-013



2013 APR 23 PM 12: 20

April 19, 2013

www.citizensbank24.com

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

RE: CON for Wellmont CVA Heart Institute - PET Camera

Dear Committee:

I am pleased to support Wellmont CVA Heart Institute's CON application for an on-site PET camera to be located at 2050 Meadowview Parkway in Kingsport.

As a diagnostic tool, Cardiac PET represents a much shorter examination time than SPECT – the typical rest/stress Cardiac PET is 30-45 minutes while the SPECT MPI exam can take 2-4 hours. Wellmont CVA Heart Institute and its 45 cardiologists are committed to the best cardiac care for our patients. This is one way that we can ensure an easier exam time for our patients, many who have difficulties lying on an exam table for an extended period of time. Also, I have read that a Cardiac PET is more accurate in obese patients than the SPECT scan which can lead to unnecessary caths.

As a corporate businessman, I thank you for your consideration of the PET camera for Wellmont CVA Heart Institute and its patients.

Sincerely,

William D. Dudney, President

Citizens Bank

101 East Main Street Kingsport, TN 37660



2013 APR 23 PN 12: 20

April 19, 2013

www.citizensbank24.com

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

RE: CON for Wellmont CVA Heart Institute - PET Camera

Dear Committee:

I am pleased to support Wellmont CVA Heart Institute's CON application for an on-site PET camera to be located at 2050 Meadowview Parkway in Kingsport.

As a diagnostic tool, Cardiac PET represents a much shorter examination time than SPECT – the typical rest/stress Cardiac PET is 30-45 minutes while the SPECT MPI exam can take 2-4 hours. Wellmont CVA Heart Institute and its 45 cardiologists are committed to the best cardiac care for our patients. This is one way that we can ensure an easier exam time for our patients, many who have difficulties lying on an exam table for an extended period of time. Also, I have read that a Cardiac PET is more accurate in obese patients than the SPECT scan which can lead to unnecessary caths.

As a corporate businessman, I thank you for your consideration of the PET camera for Wellmont CVA Heart Institute and its patients.

Sincerely

Larry Estepp Executive Vice President

Citizens Bank

101 East Main Street Kingsport, TN 37660



Partnership for Progress™

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

RE: CON for Wellmont CVA Heart Institute - PET Camera

Dear Committee:

I am pleased to support Wellmont CVA Heart Institute's CON application for an on-site PET camera to be located at 2050 Meadowview Parkway in Kingsport.

As a diagnostic tool, Cardiac PET represents a much shorter examination time than SPECT – the typical rest/stress Cardiac PET is 30-45 minutes while the SPECT MPI exam can take 2-4 hours. Wellmont CVA Heat Institute and its 45 cardiologists are committed to the best cardiac care for patients. Also, I understand that a Cardiac PET is specialized for obese patients (high body mass index – BMI.)

I urge your approval of the CON for the PET camera, and if I can be of any further service in this matter, please contact me at 423.392.8807 or mburdine@kingsportchamber.org.

Respectfully,

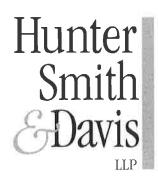
Miles Burdine

President & CEO

Kingsport Chamber of Commerce 400 Clinchfield Street, Suite 100

Md & Bi-

Kingsport, TN 37660



A Registered Limited Liability Partnership

Attorneys At Law

Established 1916

www.hsdlaw.com

writer's direct dial number: (423) 378-8829 argabrite@hsdlaw.com

S. Morris Hadden William C. Bovender William C. Argabrite Jimmie Carpenter Miller Mark S. Dessauer Gregory K. Haden Michael L. Forrester Stephen M. Darden Edward J. Webb, Jr. James N.L. Humphreys Suzanne Sweet Cook Michael S. Lattier Scott T. Powers Leslie Tentler Ridings Christopher D. Owens Chad W. Whitfield Jason A, Creech

Joseph B, Harvey
Meredith Bates Humbert
Rachel Ralston Mancl
Caroline Ross Williams
Dora A. Misciagna
Jordan Canderol: 13
Sydney Koch

Counsel

Teresa Mahan Lesnak Walter Lee Davis, Jr., Michael A. Eastridge Terry G. Kilgore Thomas R. Wilson Jeanette Smith Tysinger Kingsport, Tennessee 1212 North Eastman Road P.O. Box 3740 Kingsport, TN 37664-0740 Phone (423) 378-8800 Fax (423) 378-8809

Johnson City, Tennessee 100 Med Tech Parkway, Suite 110 Johnson City, TN 37604 Phone (423) 283-6300 Fax (423) 283-6301

> Gate City, Virginia 197 West Jackson Street P.O. Box 669 Gate City, VA 24251 Phone (276) 690-2233 Fax (276) 386-2377

PLEASE RESPOND TO:
KINGSPORT OFFICE

April 29, 2013

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Re: Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute

To CON Committee Members:

As a regional business entity headquartered in Kingsport, Tennessee, please accept this letter as our support for the CON application of Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's for a PET camera to be installed on the existing campus located at 2050 Meadowview Parkway, in Kingsport.

As the patient population in our community and region continues to age, more and more of us will encounter the need for high quality cardiac testing offering the least amount of radiation dosage. The use of a Cardiac PET scan is crucial to patients in need of cardiovascular services as this modality is more accurate in diagnosing heart disease/problems and provides a radiation dose much smaller than a Rest/Stress SPECT exam. Also, the population of Tennessee has a large percentage of obese patients and we understood that the cardiac PET scan is specialized to test patients with high body mass index (BMI).

We support this CON request with the highest regard.

Very truly yours,

HUNTER, SMITH & DAVIS, LLP

William C. Argabrite



2013 MRY 3 AM 9 26

April 24, 2013

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

Dear Sir or Madam:

I write to you to offer my personal support of the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute. As a CEO responsible for 275 employees and their families, I think there is a definite need for this tool.

I urge your support of the Wellmont cardiac PET CON application.

Sincerely

Roy L. Harmon, Jr. President and CEO

Bank of Tennessee P.O. Box 4980

Johnson City, TN 37602-4980

4/30/20C

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

To CON Committee Members:

As a businessman and citizen of Kingsport, TN, it is with great pride that I write to you to support Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be installed on the existing campus located at 2050 Meadowview Parkway, in Kingsport. As our patient population continues to age, more and more of us will exhibit the need for high quality cardiac testing offering the least amount of dose radiation. The use of a Cardiac PET scan is crucial to patients in need of cardiovascular services as this modality is more accurate in diagnosing heart disease/problems and provides a radiation dose much smaller than a Rest/Stress SPECT exam. Also, the population of Tennessee has a large percentage of obese patients and I have read that the cardiac PET scan is specialized to test patients with high body mass index (BMI).

I support this CON request with the highest regard.

Sincerely,

David S. Clark, President

Clark and Company

2020 Meadowview Parkway 2100 Recervoir Road

Kingsport, TN 37660

DRC Construction, LLC dba Clark and Company Custom Builders 2100 Reservoir Road Kingsport, TN 37660 Date 5/2/13

Health Services and Development Agency Attention: CON Reviewer/Committee Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Roger Mowen

RE: CON Application for Wellmont CVA Heart Institute - Cardiac PET Camera

Dear Committee:

I am pleased to support the Wellmont CVA Heart Institute's CON application for a fixed, on-site cardiac PET camera to be located on the Kingsport campus of the Wellmont CVA Heart Institute, which is commonly known as The Heart Center (2050 Meadowview Parkway, Kingsport).

I understand from my research that a cardiac PET camera enables advanced and very specialized non-invasive imaging for obese patients with suspected or known coronary artery disease. Due to the large amount of soft tissue in their abdomen, these patients are difficult to image using the conventional SPECT camera. Unfortunately, this region has a high concentration of obese patients and the number of obese patients is expected to increase over the next decade. A PET camera dedicated to cardiac imaging and conveniently located at The Heart Center will significantly enhance access for those patients.

I urge your approval of the CON application for the PET camera.

Sincerely,

Roger Mowen

17,24

2013 JUN 20 PM 2 14

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

To Whom It May Concern:

I write to you to offer my personal support of the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute. As a cardiologist in the Kingsport community, I wholeheartedly support this action.

As the patient population continues to grow in age and body mass, the use of the cardiac PET scan is crucial to a patient need of cardiovascular services as this modality is more accurate in diagnosing heart disease and problems in those types of patients. In obese patients, there is a high BMI level and the PET scan specializes as a diagnostic tool of this modality. A large population of my patients in the state of Tennessee deals with obesity.

Thank you for reading my letter of support. I appreciate your consideration of our PET CON.

Sincerely,

Dr. Tom Bulle 1324 Belmeade Drive Kingsport, TN 37664

2013 JUN 20 PM 2 14

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Dear Committee:

Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute has a CON application to install a PET camera at its Kingsport campus located at 2050 Meadowview Parkway in Kingsport, TN.

Cardiac PET testing is specialized for obese patients with a high body mass index. When these obese patients are tested with a SPECT scan, the interpretation is difficult and can sometimes lead to unnecessary heart catheterizations. For patients, having a Cardiac PET scan will mean a higher diagnostic sensitivity when compared to SPECT imaging resulting in fewer positive and false negative results. Our cardiologists are seeing increasing numbers of obese patients and feel strongly that the cardiac PET will provide a heightened diagnostic tool for this modality.

I urge your approval of the cardiac PET CON application.

Sincerely,

Dr. Keith Kramer

1414 Fairidge Drive Kingsport, TN 37664 State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Dear Committee:

Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute has a CON application to install a PET camera at its Kingsport campus located at 2050 Meadowview Parkway in Kingsport, TN.

Cardiac PET testing is specialized for obese patients with a high body mass index. When these obese patients are tested with a SPECT scan, the interpretation is difficult and can sometimes lead to unnecessary heart catheterizations. For patients, having a Cardiac PET scan will mean a higher diagnostic sensitivity when compared to SPECT imaging resulting in fewer positive and false negative results. Our cardiologists are seeing increasing numbers of obese patients and feel strongly that the cardiac PET will provide a heightened diagnostic tool for this modality.

I greatly support the CON application for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute.

Sincerely,

Dr. Eduardo Fernandez

21177 Walton Ridge Road

Bristol, TN 34202

2013 JUN 20 PM 2 14

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Dear Committee:

It is with great pleasure that I write you to confirm my support of Wellmont CVA Heart Institute's PET CON application. With the PET camera, patients experience a radiation dose exposure of less than one-half that of a nuclear SPECT test and one fourth of the exposure of a dual isotope. A cardiac PET scan is a specialized test for patients with a high body mass index (BMI) and the geographic population of our area experience obesity as a high risk factor.

I urge your approval of the PET camera CON on behalf of Wellmont CVA Heart Institute.

Sincerely,

2610 Halifax Drive

Kingsport, TN 37660

2013 JUN 21 AM 9 52

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Dear Committee:

It is with great pleasure that I write you to confirm my support of Wellmont CVA Heart Institute's PET CON application. With the PET camera, patients experience a radiation dose exposure of less than one-half that of a nuclear SPECT test and one fourth of the exposure of a dual isotope. Also, a cardiac PET scan is a specialized test for patients with a high body mass index (BMI) and a SPECT scan of this modality, sometimes patients receive unnecessary heart catheterizations.

Wellmont CVA Heart Institute prides itself on offering our communities the best of care while allowing the patients to stay within the comfort of their community.

I urge you to approve the CON application.

Sincerely,

Dr. Pabitra Saha

1032 Stagshaw Lane

Kingsport, TN 37660

4/16/2013

2013 JUN 20 PM 2 14

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

To CON Committee Members:

I write to you to offer my personal support of the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart.

As the patient population continues to grow in body mass, the use of the cardiac PET scan is crucial to physicians for diagnosing their patients who have obesity and high body mass index (BMI). This modality is more accurate in diagnosing heart disease and problems in these types of patients.

Thank you for reading my letter of support. I appreciate your approving the PET CON application.

Sincerely,

Dr. Chris Kennedy 134 Trammell Road Bristol, TN 37621

2013 JUN 21 AM 9 55

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Dear CON Committee Members:

It is my pleasure to write you on behalf of Wellmont CVA Heart Institute in support of its CON application for a PET camera. As a cardiologist, I applaud Wellmont CVA Heart Institute's dedication to our patients to provide excellent cardiac care to my patients, friends, family, and communities that we represent.

As you know, heart disease and stroke are leading causes of death in the United States. I have witnessed that Wellmont CVA Heart Institute is committed to improving access to health care close to home and to providing the technology to diagnose heart disease in the most medically appropriate manner. The state of Tennessee has a high obese population with a high body mass index (BMI) and I recognize that these patients are better served with a cardiac PET scan rather than a SPECT scan. The SPECT scan's results are hard to interpret in obese patients and this sometimes leads to unnecessary heart catheterizations.

I support the CON request for a PET camera at Wellmont CVA Heart Institute located at 2050 Meadowview Parkway, Kingsport, TN.

Thank you for your consideration of our request.

Sincerely,

Dr. Brian Dulin 1110 Timbers East Greeneville, TN 37745 9/ / 왕/ / 3 Date

2013 JUN 21 AM 9 56

State of Tennessee Health Services and Development Agency Frost Building, 3rd floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Distinguished Committee Members:

As a physician, I want to let you know of my support for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's application to install a Cardiac PET camera on its existing campus in Kingsport.

Wellmont CVA Heart Institute is a dedicated corporate citizen to our communities, responding not only to the needs of the patients it serves, but to the healthcare needs of entire communities. Wellmont CVA Heart Institute's community benefit contribution to this area is significant. As a cardiologist, a cardiac PET scan provides us with specialized test for obese patients with a high body mass index (BMI). When these obese patients were tested with a SPECT scan, the interpretation was difficult and sometimes lead to unnecessary heart catheterizations.

I strongly support the CON application for the PET camera for Wellmont CVA Heart Institute.

Sincerely,

Dr. Larry Cox 17502 Thomas Court

Abingdon, VA 24211

17-13

Distinguished Committee Members:

I write to you to personally express my support of Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be located on the existing campus at 2050 Meadowview Parkway, in Kingsport.

With heart disease and stroke as leading causes of death in the United States, Wellmont CVA Heart Institute commits itself to improving access to cardiac health care close to home. Our patients appreciate the opportunity to seek high quality cardiac care offering the best technologies available right here at home. Having the cardiac PET scan here will allow the cardiologists an excellent diagnostic tool for obese patients with a high body mass index as the PET camera is specialized for this modality.

On behalf of Kingsport and our surrounding communities, please accept my letter of support and the urge to approve the CON request.

Thank you.

Dr. Chris Metzger

1004 Stagshaw Lane

Kingsport, TN 37660

4/12/13

2013 JUN 25 AM 8 02

State of Tennessee
Health Services and Development Agency
Frost Building, 3rd Floor
161 Rosa L. Parks Blvd.
Nashville, TN 37243

Dear CON Committee:

Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute has a CON application to install a PET camera at its Kingsport campus located at 2050 Meadowview Parkway in Kingsport, TN.

Cardiac PET testing is specialized for obese patients with a high body mass index. When these obese patients are tested with a SPECT scan, the interpretation is difficult and can sometimes lead to unnecessary heart catheterizations. For patients, having a Cardiac PET scan will mean a higher diagnostic sensitivity when compared to SPECT imaging resulting in fewer positive and false negative results. Our cardiologists are seeing increasing high numbers of obese patients and feel strongly that a cardiac PET scan will provide a heightened diagnostic tool for this modality.

I urge your approval of the cardiac PET CON application.

Sincerely

Dr. Cary Meyers 2216 Valley Falls Ct.

Kingsport, TN 37664

2013 JUN 26 AM 9 11

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Dear CON Committee Members:

It is my pleasure to write you on behalf of Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute in support of its CON application for a PET camera.

Heart disease and stroke are leading causes of death in the United States. The state of Tennessee has a high obese population and I recognize that these patients are better served with a cardiac PET scan rather than a SPECT scan as the cardiac PET is specialized for this modality. The SPECT scan's results are hard to interpret in obese patients and this sometimes leads to unnecessary heart catheterizations.

I support the CON request for a PET camera at Wellmont CVA Heart Institute located at 2050 Meadowview Parkway, Kingsport, TN.

Thank you for your consideration of our request.

Sincerely,

Dr. Andrew Cross 140 Park Drive

Jonesborough, TN 37659

17 Apr. (, 2013 Date

To CON Committee Members:

Please accept my support for a PET camera to be installed at Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's existing Kingsport campus located at 2050 Meadowview Parkway, Kingsport, TN.

Our patient population continues to grow in body mass, and the use of the cardiac PET scan is crucial to an obese patient as the cardiac PET scan is more accurate in diagnosing heart disease and problems in these types of patients. In these obese patients, there is a high body mass index (BMI) and the PET scan specializes as a diagnostic tool of this modality. A large population in the state of Tennessee deals with obesity.

Thank you for reading my letter of support. I appreciate your consideration of our PET CON.

Sincerely,

Dr. Scott Jay

173 John Matthews Road Limestone, TN 37681

2013 JUN 26 AM 9 11

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

To CON Committee Members:

I support the CON application for a PET Camera to be installed on the existing campus of Kingsport's Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute.

Our patients will benefit from the reduced radiation dose exposure with Cardiac PET – it is less than ½ that of the Tc-99 based Single Isotope SPECT. Also, with a large population of obese patients (high BPI) in our geographic region, these patients cannot be evaluated well with SPECT which can lead to unnecessary cardiac catheterizations. The cardiac PET is specialized to diagnose this modality.

I urge you to approve this PET CON application.

Sincerely,

Dr. Marcus Williams

4 Phillip Ct.

Johnson City, TN 37604

4/23/13

2013 JUN 26 AM 9 11

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, 'TN 37243

To CON Committee Members:

As a cardiologist, it is with great pride that I write to you to support Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be installed on the existing campus located at 2050 Meadowview Parkway, in Kingsport.

As our patient population continues to age, more and more of us will exhibit the need for high quality cardiac testing offering the least amount of dose radiation. The use of a Cardiac PET scan is crucial to patients in need of cardiovascular services as this modality is more accurate in diagnosing heart disease/problems and provides a radiation dose much smaller than a Rest/Stress SPECT exam. Also, the population of Tennessee has a large percentage of obese patients and the cardiac PET scan is specialized to test patients with high body mass index (BMI).

I support this CON request with the highest regard.

Sincerely,

Dr. Jon Burress 531 Sandbar Road

Bristol, TN 37620

4/20 Date

To CON Committee:

Thank you for consideration of the CON application for a PET camera to be installed at Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute located at 2050 Meadowview Parkway in Kingsport, TN.

Our cardiologists are committed to excellence in service and we feel that a PET camera will enable our patients a shorter examination time than the Rest/Stress SPECT exam resulting in a shorter time on the exam table which can be quite uncomfortable for our aged patients. Further, patients with a high body mass index (BMI) receive a heightened level of testing as the Cardiac PET is specialized for obesity. In an obese patient receiving a SPECT scan, the interpretations are difficult which can result in an unnecessary heart catheterization.

Please accept my letter of support.

Sincerely,

Dr. Orson Go

Sportswise Apartments, Apt. #215B

215 E. Main Street Wise, VA 24293 4/24/13

2013 JUN 26 AM 9 11

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

To CON Committee Members:

It is my pleasure to support the CON application for a PET Camera to be installed on the existing campus of Kingsport's Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute.

Wellmont CVA Heart Institute is a dedicated corporate citizen to this community and the communities surrounding us and they not only respond to the health care needs of its patients, but to the healthcare needs of the entire community.

It is with this commitment to provide the highest level of cardiac care that I urge you to approve this certificate of need. Our patients will benefit from the reduced radiation dose exposure with Cardiac PET – it is less than ½ that of the Tc-99 based Single Isotope SPECT. With a large population of obese patients (high BMI), these patients cannot be evaluated well with SPECT which can lead to unnecessary cardiac catheterizations. The cardiac PET is specialized to diagnose this modality.

Thank you for your strong consideration of this CON request.

Dr. Pavan Karnati

175 Greatview Road

Cedar Bluff, VA 24609

2013 JUL 1 AM 9 08

To Whom It May Concern:

I write to you to offer my personal support of the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute. As a cardiologist in the Kingsport community, I wholeheartedly support this action.

Cardiac PET is crucial to providing an accurate cardiovascular testing tool for patients who have an obesity risk factor and a high body mass index (BMI) and a large population of patients in the state of Tennessee deal with obesity.

Thank you for supporting the CON application for a PET camera.

Sincerely,

Dr. Collier Jordan

413 Shade Tree Way

Johnson City, TN 37604

Data

Distinguished Committee Members:

I write to you to personally express my support of Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be located on the existing campus at 2050 Meadowview Parkway, in Kingsport.

With heart disease and stroke as leading causes of death in the United States, Wellmont CVA Heart Institute commits itself to improving access to cardiac health care. Our patients appreciate the opportunity to seek high quality cardiac care offering the best technologies available right here at home. Having the cardiac PET scan here will allow us an excellent diagnostic tool for obese patients with a high body mass index (BMI) as the PET camera is specialized for this modality. If having a SPECT test, some patients receive unnecessary heart catheterizations.

On behalf of Kingsport and our surrounding communities, please accept my letter of support and the urge to approve the CON request.

Thank you.

Dr. Gerald Blackwell 1733 Orchard Court

Kingsport, TN 37660

To CON Committee:

Please accept my support of the CON application for a PET camera to be installed at Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute located at 2050 Meadowview Parkway in Kingsport, TN.

As a cardiologist, we are committed to excellence in service and we feel that a PET camera will enable our patients a shorter examination time than the Rest/Stress SPECT exam resulting in a shorter time on the exam table which can be quite uncomfortable for our aged patients. Further, patients with a high body mass index (BMI) receive a heightened level of testing as the Cardiac PET is specialized for obesity. In an obese patient receiving a SPECT scan, the interpretations are difficult which can result in an unnecessary heart catheterization.

I urge your approval.

Sincerely,

Dr. Matt Luff

15250 Knob Hill Drive

Bristol, VA 24202

To CON Committee Members:

It is with great pride that I write to you to support Wellmont Cardiology Services db/a Wellmont CVA Heart Institute's CON application for a PET camera to be installed on the existing campus located at 2050 Meadowview Parkway, in Kingsport.

As our patient population continues to age, more and more of us will exhibit the need for high quality cardiac testing offering the least amount of dose radiation. Also, in this geographic area, our population has a high risk factor of obesity (BMI). The use of a Cardiac PET scan is crucial in the diagnosis of obese patients as cardiac PET is specialized for this modality. Further, it provides a radiation dose much smaller than a Rest/Stress SPECT exam.

I support this CON request with the highest regard.

Sincerely,

Dr. Jeffrey Kappa 153 Oak Grove Loop

Gray, TN 37615

Di

Man a. Acrackomo

To Whom It May Concern:

I write to you to offer my personal support of the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute. As a cardiologist, I wholeheartedly support this action.

As the patient population continues to grow in age and body mass, the use of the cardiac PET scan is crucial to a patient need of cardiovascular services as this modality is more accurate in diagnosing heart disease and problems in those types of patients. In obese patients, there is a high BMI level and the PET scan specializes as a diagnostic tool of this modality. A large population in the state of Tennessee deals with obesity.

Thank you for reading my letter of support. I appreciate your consideration of our PET CON.

4/17//3 Date

Sincerely,

Dr. Mark Borsch 117 Quail Run

Bristol, TN 37620

Dear Committee:

I write you to confirm my support of Wellmont CVA Heart Institute's PET CON application. With the PET camera, patients experience a radiation dose exposure of less than one-half that of a nuclear SPECT test and one fourth of the exposure of a dual isotope. A cardiac PET scan is a specialized test for patients with a high body mass index (BMI) and those patients who receive a SPECT scan sometimes receive an unnecessary heart catheterization.

I urge you to approve the CON application.

Sincerely,

Dr. Grøgory Uhl 105 High Street

Greeneville, TN 37745

4/24/2013 Date

Distinguished Committee Members:

I write to you to personally express my support of Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be located on the existing campus at 2050 Meadowview Parkway, in Kingsport.

With heart disease and stroke as leading causes of death in the United States, Wellmont CVA Heart Institute commits itself to improving access to cardiac health care close to home. Our patients appreciate the opportunity to seek high quality cardiac care offering the best technologies available right here at home. Having the cardiac PET scan here will allow the cardiologists an excellent diagnostic tool for obese patients with a high body mass index as the PET camera is specialized for this modality.

On behalf of Kingsport and our surrounding communities, please accept my letter of support and the urge to approve the CON request.

Thank you.

Dr. Pierre Istfan

1113 Mountain Vista Drive

Bristol, TN 37620

2013 JUL 9 AM 10 15

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

To CON Committee:

Please accept my support of the CON application for a PET camera to be installed at Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute located at 2050 Meadowview Parkway in Kingsport, TN.

A PET camera will enable cardiac patients a shorter examination time than the Rest/Stress SPECT exam resulting in a shorter time on the exam table which can be quite uncomfortable for aged patients. Further, patients with a high body mass index (BMI) receive a heightened level of testing as the Cardiac PET is specialized for obesity. In an obese patient receiving a SPECT scan, the interpretations are difficult which can result in an unnecessary heart catheterization.

I urge your approval.

Sincerely,

Dr. Sarfraz Zaidi

P. O. Box 1153 Bristol, TN 37621

2013 JUL 9 AM 10 15

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

To CON Committee:

Thank you for consideration of the CON application for a PET camera to be installed at Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute located at 2050 Meadowview Parkway in Kingsport, TN.

Our patients will have a shorter examination time than with Rest/Stress SPECT resulting in a shorter time on the exam table which can be quite uncomfortable for our aged patients. Further, patients with a high body mass index (BMI) receive a heightened level of testing as the Cardiac PET is specialized for obesity. In an obese patient receiving a SPECT scan, the interpretations are difficult which can result in an unnecessary heart catheterization.

Lurge your support of this CON application.

Sincerely,

Dr. Harry Turner 3425 Parkcliff Drive Kingsport, TN 37664

2013 JUL 9 AM 10 15

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

To Whom It May Concern:

I write to you to offer my personal support of the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute. As a cardiologist, I wholeheartedly support this action.

As the patient population continues to grow in age and body mass, the use of the cardiac PET scan is crucial to a patient need of cardiovascular services as this modality is more accurate in diagnosing heart disease and problems in those types of patients. In obese patients, there is a high BMI level and the PET scan specializes as a diagnostic tool of this modality. As our baby boomers age, we feel strongly that we want the best cardiac testing procedures available close to home.

Thank you for reading my letter of support. Please approve the CON for a PET camera.

Sincerely,

Dr. John Berry 5328 Foxfire Place

Kingsport, TN 37664

To CON Committee Members:

I write to you to offer my personal support of the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute. As a cardiologist in our community, I wholeheartedly support this action.

As the patient population continues to grow in body mass, the use of the cardiac PET scan is crucial to patients needing cardiovascular diagnostic services as this modality is more accurate in diagnosing heart disease and problems in these types of patients. In obese patients, there is a high BMI level and the PET scan specializes as a diagnostic tool of this modality. The obese patients who have a SPECT scan sometimes receive an unnecessary hearth catheterization. I can attest that a large population of my patients in our geographic area deal with obesity.

Thank you for reading my letter of support. I appreciate your consideration of our PET CON.

Sincerely,

Dr. Herb Ladley

1532 E. Sevier Avenue

Kingsport, TN 37660

Dear Committee:

Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute has a CON application to install a PET camera at its Kingsport campus located at 2050 Meadowview Parkway in Kingsport, TN.

As a cardio-thoracic surgeon, Cardiac PET testing is specialized for obese patients with a high body mass index. When these obese patients are tested with a SPECT scan, the interpretation is difficult and can sometimes lead to unnecessary heart catheterizations. Patients having a Cardiac PET scan will mean a higher diagnostic sensitivity when compared to SPECT imaging resulting in fewer positive and false negatives resulting in an excellent diagnostic tool.

I greatly support the CON application for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute.

Sincerely,

Dr. Tyler Greenfield 222 Southwood Drive Kingsport, TN 37664

2013 JUL 5 AM 9 06

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Dear Committee:

Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute has a CON application to install a PET camera at its Kingsport campus located at 2050 Meadowview Parkway in Kingsport, TN.

Cardiac PET testing is specialized for obese patients with a high body mass index. When these obese patients are tested with a SPECT scan, the interpretation is difficult and can sometimes lead to unnecessary heart catheterizations. For patients, having a Cardiac PET scan will mean a higher diagnostic sensitivity when compared to SPECT imaging resulting in fewer positive and false negative results. Our cardiologists are seeing increasing numbers of obese patients and feel strongly that the cardiac PET will provide a heightened diagnostic tool for this modality.

I greatly support the CON application for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute.

Sincerely,

Dr. Anilkumar Joshi

1237 Virginia Avenue #4A

Norton, VA 24273

2013 JUL 5 AM 9 06

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

Distinguished Committee Members:

I write to you to personally express my support of Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be located on the existing campus at 2050 Meadowview Parkway, in Kingsport.

With heart disease and stroke as leading causes of death in the United States, Wellmont CVA Heart Institute commits itself to improving access to cardiac health care. Having the cardiac PET scan here will allow us an excellent diagnostic tool for obese patients with a high body mass index (BMI) as the PET camera is specialized for this modality. If having a SPECT test, some patients receive unnecessary heart catheterizations.

I urge your support of this CON application.

Thank you.

Dr. Freddie Williams 1009 Hanover Court Kingsport, TN 37660

Dear Committee:

It is with great pleasure that I write you to confirm my support of Wellmont CVA Heart Institute's PET CON application. With the PET camera, our patients experience a radiation dose exposure of less than one-half that of a nuclear SPECT test and one fourth of the exposure of a dual isotope. Also, a cardiac PET scan is a specialized test for patients with a high body mass index (BMI). The obese patient ratio in the state of Tennessee is quite high. Wellmont CVA Heart Institute prides itself on offering our communities the best of care while allowing the patients to stay within the comfort of their community.

Thank you for your consideration of the PET camera CON on behalf of Wellmont CVA Heart Institute. I urge your support and approval of this CON request.

Sincerely,

Dr. Clair Hixson

1813 Fleetwood Drive

Kingsport, TN 37660

15 April 2013

2013 JUL 11 AM 9 11

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

To CON Committee Members:

As a cardiologist in Kingsport, TN, it is with great pride that I write to you to support Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be installed on the existing campus located at 2050 Meadowview Parkway, in Kingsport.

As our patient population continues to age, more and more of us will exhibit the need for high quality cardiac testing offering the least amount of dose radiation. The use of a Cardiac PET scan is crucial to patients in need of cardiovascular services as this modality is more accurate in diagnosing heart disease/problems and provides a radiation dose much smaller than a Rest/Stress SPECT exam. Also, the population of Tennessee has a large percentage of obese patients and the cardiac PET scan is specialized to test patients with high body mass index (BMI).

I support this CON request with the highest regard.

Besturo MD FACE

Sincerely,

Dr. John Bertuso 1108 Norfolk Place

Kingsport, TN 37660

Data

2013 JUL 11 AM 9 11

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

To CON Committee:

I support the PET camera CON application presently under your consideration for Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute. As a cardiologist in the Kingsport community, I wholeheartedly support this action.

As the patient population continues to grow in age and body mass, the use of the cardiac PET scan is crucial to a patient need of cardiovascular services as this modality is more accurate in diagnosing heart disease and problems in those types of patients. In obese patients, there is a high BMI level and the PET scan specializes as a diagnostic tool of this modality. A large population of my patients in the state of Tennessee deal with obesity in increasing numbers.

I urge your approval of this CON certificate of need request.

Sincerely,

Dr. Arun Rao 1072 Timberidge Trail

Kingsport, TN 37660

Dear Committee:

I write you to confirm my support of Wellmont CVA Heart Institute's PET CON application. With the PET camera, patients experience a radiation dose exposure of less than one-half that of a nuclear SPECT test and one fourth of the exposure of a dual isotope. A cardiac PET scan is a specialized test for patients with a high body mass index (BMI) and those patients who receive a SPECT scan sometimes receive an unnecessary heart catheterization.

I urge you to approve the CON application.

Sincerely,

Dr. Jay Merrill

416 Canongate Road Kingsport, TN 37660 Date

4/17/13

To CON Committee:

Thank you for consideration of the CON application for a PET camera to be installed at Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute located at 2050 Meadowview Parkway in Kingsport, TN.

Committed to excellence in patient care, our cardiologists feel that a PET camera will enable our patients a shorter examination time than the Rest/Stress SPECT exam resulting in a shorter time on the exam table which can be quite uncomfortable for our aged patients. Further, patients with a high body mass index (BMI) receive a heightened level of testing as the Cardiac PET is specialized for obesity.

I urge you to approve this certificate of need application.

Sincerely

Dr. Jøe Bailey

313 Huntington Way Johnson City, TN 37604

19 april 2013

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Boulevard Nashville, TN 37243

To CON Committee Members:

I support the CON application for a PET Camera to be installed on the existing campus of Kingsport's Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute.

Wellmont CVA Heart Institute is a dedicated corporate citizen to this community and the communities surrounding us and they not only respond to the health care needs of its patients, but to the healthcare needs of the entire community. The benefit that Wellmont CVA Heart Institute provides to our area is significant.

With a large population of obese patients (high BMI), these patients cannot be evaluated well with SPECT which can lead to unnecessary cardiac catheterizations. Our patients will benefit from the reduced radiation dose exposure with Cardiac PET – it is less than ½ that of the Tc-99 based Single Isotope SPECT.

I urge you to approve the PET CON application..

Jack Whitaker

277 Brethren Church Drive Jonesborough, TN 37659

Distinguished Committee Members:

As a cardiologist, it is with much excitement that I write to you to personally express my support of Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be located on its existing campus at 2050 Meadowview Parkway, in Kingsport.

As you already know, heart disease and stroke are leading causes of death in the United States. Wellmont CVA Heart Institute commits itself to improving access to health care close to home. Here in Kingsport, we have a high educated retirement population due to the presence of Eastman Chemical and the beauty of our area with mountains and lakes offering a serene setting. Our citizens are very in tune with their health and appreciate the opportunity to seek high quality cardiac care with the best technologies available right here at home. The Cardiac PET scan is a specialized test to diagnose patients who are obese with a high body mass index (BMI).

On behalf of Kingsport and our surrounding communities, please accept my letter of support.

7 /

Thank you.

Dr. Harold Alison 1334 Pickens Bridge Road

Piney Flats, TN 37604

2013 JUL 17 AM 9 14

State of Tennessee Health Services and Development Agency Frost Building, 3rd Floor 161 Rosa L. Parks Blvd. Nashville, TN 37243

To CON Committee Members:

I write to you to support Wellmont Cardiology Services d/b/a Wellmont CVA Heart Institute's CON application for a PET camera to be installed on the existing campus located at 2050 Meadowview Parkway, in Kingsport.

As our patient population continues to age, more and more of us will exhibit the need for high quality cardiac testing offering the least amount of dose radiation. Also, in this geographic area, our population has a high risk factor of obesity. The use of a Cardiac PET scan is crucial in the diagnosis of obese patients as cardiac PET is specialized for this modality. Further, it provides a radiation dose much smaller than a Rest/Stress SPECT exam.

I support this CON request.

Sincerely,

Dr. Dan Simpson

4840 Preston Park Drive

Kingsport, TN 37660

4/17/13 Date